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MONTEREY, CALIFORNIA

THESIS

**TECHNICAL MODIFICATION WITHIN THE
HEALTHCARE INDUSTRY: IMPROVING BOTH THE
EFFICACY OF THE NATIONAL DRUG CODE CARRIER
AND THE ACCESSIBILITY OF ELECTRONIC HEALTH
RECORDS TO REDUCE ADVERSE DRUG EVENTS**

by

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CARRIER AND THE ACCESSIBILITY OF ELECTRONIC HEALTH RECORDS
TO REDUCE ADVERSE DRUG EVENTS**

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ABSTRACT

The main focus of this thesis is to present the idea that QR codes could contribute to a reduction in adverse drug events (ADEs) by increasing the efficacy of the national drug code and storing an electronic health record. This research examines a change in drug coding technology that will decrease the number of ADEs by empowering patients' to be more proactive in tracking their current prescription and over-the-counter drugs, and the ADEs associated with them. The main objectives of this research are to demonstrate the benefits of replacing the National Drug Code carrier, discuss how these benefits will decrease ADEs, and associate electronic health records with ADE reduction. Our recommendation to replace the current one-dimensional barcode with a two-dimensional barcode known as Quick Response (QR) code will allow both patient access and drug awareness software application compatibility. This research also provides relevant information to the use of the QR code such as the following: information to be stored, practical hardware devices for patients' to access information, and software applications that can contribute to decreased ADEs.

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LIST OF ACRONYMS AND ABBREVIATIONS

ADE	Adverse Drug Events
AMA	American Medical Association
CDC	Center for Disease Control
EHR	Electronic Health Record
EMR	Electronic Medical Record
EMT	Emergency Medical Technician
FDA	Food and Drug Administration
HIPAA	Health Insurance Portability and Accountability Act
HITECH	Health Information Technology for Economic and Clinical Health
IOM	Institute of Medicine
ISO	International Standard Organization
NDC	National Drug Code
ONC	Office of the National Coordinator for Health Information Technology
OTC	Over-the-Counter
PHI	Personal Health Information
QR	Quick Response
SWOT	Strengths, Weaknesses, Opportunities, and Threats
UPC	Universal Product Code

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I. INTRODUCTION

A. OVERVIEW

According to the Center for Disease Control (CDC), adverse drug events (ADEs) are responsible for 700,000 emergency department visits and 120,000 hospitalizations each year, and these numbers will likely grow (Center for Disease Control [CDC], 2010). ADEs kill over 100,000 people each year, and the more drugs a patient is taking, the higher the chance that he or she will fall victim to ADEs (Food and Drug Administration [FDA], 2009). In response, this research examines a change in drug coding technology that will decrease the number of ADEs by empowering patients' to be more proactive in tracking their current prescription and over-the-counter (OTC) drugs, and the ADEs associated with them. We will examine the current National Drug Code (NDC) and its one-dimensional barcode used for pharmaceutical logistics as well as other one and two-dimensional barcode methods for storing information. We will then provide our recommendation to replace the current one-dimensional barcode with a two-dimensional barcode known as Quick Response (QR) code to will allow both patient access and drug awareness software application compatibility. Once the two-dimensional barcode recommendation has been established, we will provide relevant information to the use of the barcode such as the following: information to be stored, practical hardware devices for patients' to access information, and software applications that can contribute to decreased ADEs.

B. STATEMENT OF THE PROBLEM

In the United States, over 100,000 people die annually from ADEs (FDA, 2009). Many of these ADEs are the result of adverse interactions from multiple medications (FDA, 2009). It has been shown that the more drugs a patient is taking, the higher the risk for an interaction (FDA, 2009). According to a study of drug interactions in an emergency department, interactions were present in 16 percent of the patients' in the study who were taking two or more drugs. Of that

16 percent, those who were taking at least seven drugs had a 100 percent interaction (Karas, 1981). A study on healthcare dissatisfaction that involved the United States, United Kingdom, Canada, New Zealand, and Australia, revealed that two-thirds of adults in each country reported taking prescription drugs on a regular basis. Adults from the United States were more likely to report taking four or more prescription drugs as opposed to adults in the other countries (Blendon, Schoen, DesRoches, Osborn, & Zapert, 2003). It is common for adults in the United States to take multiple medications. This presents a real problem in the prevention of ADEs. The large human and economic costs due to adverse drug interactions can be attributed to many factors, including the heterogeneous nature of healthcare where a patient may see many disparate physicians often resulting in incomplete or erroneous drug records, and a lack of tools to educate and empower patients to manage their own well-being. Existing systems that allow patients to access and manage their medications are not effective because the information either does not exist, is too difficult for patients to access or understand, is too limited to make meaningful decisions or cannot be easily uploaded to software applications that store and provide drug information and interaction details.

C. PURPOSE OF THE PROJECT

The purpose of this research is to explain how Quick Response (QR) codes may augment existing prescription and over-the-counter labels such as the National Drug Code, creating a more efficacious way to store drug information. This study will also provide a solution for increasing patient awareness and knowledge of his or her drug record by improving access to pertinent information for prescription medications, OTC drugs, and supplements, in order to help reduce adverse drug events and increase the preciseness of patients' drug lists. This is important because ADEs that may result from incorrect drug lists or a patients' lack of knowledge have significant human and healthcare costs. The results of this study will provide a roadmap for improving the efficacy of the NDC,

bridging the gap that currently exist between patients and their drug record, and through survey results, provide guidance for what kind of information should be stored on the QR codes.

D. RESEARCH QUESTIONS

- What technological modification will improve the efficacy of the National Drug Code?
- What are the benefits of replacing the National Drug Code with this modification?
- How will the benefits help reduce adverse drug events?
- What type of information should the modified National Drug Code contain in order to contribute to the above benefits?
- What role do Electronic Health Records play in obtaining medication information?
- What technological modification will improve the accessibility of Electronic Health Records?
- What are the benefits of using this technological modification to obtain Electronic Health Records?
- How will the benefits of accessing EHRs help reduce adverse drug events?

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II. BACKGROUND

A. ADVERSE DRUG EVENTS

1. Background

ADEs are responsible for 700,000 emergency department visits and 120,000 hospitalizations each year, and these numbers will likely grow (CDC, 2010). Increasing patient medications and supplements, contribute to killing over 100,000 people each year, because the more drugs a patient is taking, the higher the chance that he or she will fall victim to ADEs because of a drug to drug interaction (FDA, 2009). Other obvious contributing factors are a lack of provider continuity, and a lack of an adequate drug tracking systems for both patients and provider. Each year, one in three older adults who are taking more than five medications will experience an ADE (Edlin, 2010). One-third to one-half of ADEs are caused by human error (Sun & Zhou, 2011).

Several definitions of ADEs exist, but results from research and case studies provided by the Annals of Internal Medicine (2004) suggests the use of the Institute of Medicine's (IOM) definition of an adverse drug event, which states, "an injury resulting from the use of a drug." The term ADE was chosen because of its broad definition. Various literature reviews have indicated that other definitions of ADEs coincide more with adverse drug reactions, which can be covered under the term ADE (Nebeker, Barach, & Samore, 2004).

The factors that contribute to ADEs are mostly human related and are prevalent in clinics, hospitals, home healthcare settings, and retirement homes while involving doctors, patients, and family members. For example, factors that contribute to ADEs developed after a patient is discharged from a hospital (refer to Table 1) can also be applied to the other settings that were previously mentioned.

Table 1: Factors contributing to adverse drug events (ADEs) that develop after a patient's discharge from hospital		
Factor	Description	Implications for discharge planning
Changing medications	All medications have an inherent risk of side effects. Most ADEs become apparent shortly after initiating treatment. Errors in administration occur, likely because of unfamiliarity.	Put or keep a system in place to monitor patients for new symptoms or errors during the first few days after discharge
Changing metabolic requirements	Dietary modifications, changes in hepatic or renal function, or co-administration of specific drugs often necessitate dose adjustments or even stopping a medication.	Pay special attention to patients: <ul style="list-style-type: none"> • with altered renal or hepatic function • whose medication habits must change
Multiple prescriptions	Because each medication is associated with risk of an ADE, such events become more likely as the number of concurrent medications increases.	Ensure that patients taking 8 or more medications are adequately educated and monitored
Inadequate preparations for discharge	Many patients do not recall being taught about the side effects of their medications. They often feel inadequately prepared by hospital staff to manage their care at home.	Educate patients about their medications, the side effects they may expect and the monitoring required, beginning in the hospital and continuing afterward
High-risk medications	High-risk drugs that are commonly prescribed include warfarin, glucocorticoids, antibiotics, narcotic analgesics and hypoglycemic medications.	Pay special attention to patients receiving high-risk medications Plan for monitoring (e.g., INR tests)
Poor integration and coordination of care	Discharge summaries are often not received. Systems of care for monitoring patients in the days after their discharge from hospital are inadequate.	Prepare a structured discharge summary Provide and distribute it promptly Routinely check on patients out of hospital

Note: INR = international normalized ratio.

Table 1. Factors contributing to ADSs that develop after a patient's discharge from hospital (From Forster, 2006)

2. Reduction Methods and Applications

A patient safety “best practice” is one way to prevent ADEs. By calling for “clinicians to enlist patients as partners,” clinicians can make better treatment decisions through engaging and educating the patients and their families (Weingart et al., 2004). This “best practice” is recommended based on the following observations: it is possible for patients and families to identify deficiencies in healthcare; a patient may have personal health information that may not be accessible if the patient is seen at multiple practices; and the successful delivery of outpatient care depends on patient adherence (Weingart et al., 2004). Preventing ADEs is an organized multidisciplinary approach (Forster, 2006). It requires communication and understanding from all parties involved. Suggested actions to prevent ADEs shows evidence that knowledge and strong communication between a patient and his or her provider are key concepts. According to the Joanna Briggs Institute, 2006, a lack of knowledge of the drug is the most common cause of medications errors in the United States. To give

relative examples of ADE prevention methods, the following eight points taken from Forster (2006), are suggested actions that can help a physician reduce ADEs:

- Communicate explicitly as to which of the pre-hospital medications need to be changed or stopped.
- Provide an accurate, legible medication profile to the patient and his or her pharmacist, physician and other community care providers. Included on this list should be the indications for the medications and the reason for any changes in dosage. Include the prescribing physician's contact information as well, so that questions can be easily directed.
- Advise patients to bring all existing medications from home along with their new prescriptions when they go to the pharmacy, so any discrepancies can be quickly resolved.
- Educate patients on the side effects of medications, especially new or high-risk medications (Table 1). Patients need to recognize a side effect when they experience one, as well as to know what to do and whom to call.
- Ensure that the patient is aware of any medications that require laboratory monitoring, when tests should be performed and who is responsible to respond to the results.
- If multidisciplinary sources of information on drug use exist (e.g., nurses or clinical pharmacists who teach inhaler or injection techniques), ensure that they are engaged before patient discharge. Enlist the aid of community pharmacists and nurses to provide ongoing education and support for the discharged patient.
- Provide timely communication to community-based physicians. An interim discharge summary should be faxed to the primary care physician and a copy given to the patient. The discharge summary needs to be dictated (and, one hopes, transcribed) on the day of discharge and copies must be sent to all relevant caregivers.
- Whenever possible (and assuming the patient consents), enlist family members or other supportive people to help monitor patients, arrange follow-up and ensure that medications are accurately administered at home.

The knowledge and communicative actions that need to exist between patients and their providers are more prevalent in cases involving older adults. If managing medications is already a challenge among older adults today, and obvious trends point toward an increasing number of older adults that will require

care in the future, it is imperative that methods to prevent ADEs become a priority among researches. Older adults, especially those with multiple chronic conditions, experience multiple transitions of care and multiple providers (Siek, Khan, Ross, Haverhals, Meyers, & Cali, 2004; Edlin, 2010). These transitions make sharing and communicating personal health information (PHI) more difficult. Communication is also more difficult in older adults because there are more people involved in their care such as multiple providers (during transitions), caregivers, and family members.

3. Applications for Supporting ADE Reduction Methods

There are many applications that exist in helping patients become more aware of the medications that they are taking. As previously mentioned, one of the contributors to ADEs is a patient's lack of awareness about the medication that he or she is taking. The lack of awareness can be influenced by not having a clear understanding about the medication being taken, how to take it, when to take it, or what not to take with it (contributing to an adverse drug reaction). Although not all of these factors of knowledge may contribute directly to an ADE, they contribute to a lack of awareness and familiarization that aids in properly communicating a medication list to a provider during multiple transitions among treatment facilities and pharmacies.

There is software that helps patients familiarize themselves with their medications, store prescriptions and provider reminders for taking the medication as well as the correct dosage. For example, Med Helper, Rx Case Minder, and Rx pal are available for the Android platform. Windows compatible applications include Medication Tracker, Rx Reminder, and Tablet Time. RxmindMe is compatible with Apple products such as the iPhone, iPad, and iPod touch (Clarity Digital Group, 2012).

Walgreens.com, CVS.com, and RiteAid.com are examples of websites of major drug store chains that provide customers with iOS and Android applications that connect them to many of the services that each store provides.

Among the services that these applications provide are prescription refills, prescription transfers, and pill reminders. These software applications allow a smartphone to scan the one-dimensional barcodes on the prescription medicine bottles. The prescription number can also be manually inputted.

Beyond tracking medication, there exist websites, such as drugdigest.org, medscape.com, and caremark.com, which offer users an opportunity to learn about the potential for interactions between drugs. These drug interaction websites provide a searchable database that allows a user to enter the names of medications and get results of whether there are potential interactions.

Drugdigest.org, sponsored and funded by Express Scripts, Inc., does not require registration and is very user friendly (Drug Digest, 2012). The “check interactions” tab on the Web page takes a user to a search field where a user can type in and select two or more drugs and then check his or her interactions. As an example checking the interactions of two non-steroidal anti-inflammatory drugs (NSAIDs), Ibuprofen and Naproxen, results in having “no interactions” (see Figures 1 and 2). In addition, when checking the interaction of Coumadin and Aspirin, it results in having four potential interactions (see Figures 3 and 4).

Check Interactions

Check potential interactions™ between two or more drugs (complete instructions below):

Drug

Search Results

- 2-Amino-2-Deoxyglucose
- 2-Dimethyl aminoethanol
- 2-Dimethylaminoethanol
- 24-alpha-ethylcholestanol
- 3-beta,5-alpha-stigmastan-3-ol
- 3TC
- 3TC and AZT
- 3TC and ZDV
- 4% Skin Bleaching Topical Gel

Interaction List

- Ibuprofen Capsules
- Naproxen Tablets

☒ Check Interactions with Food and Alcohol

Figure 1. Checking the interaction between two NSAIDs
(From Drug Digest, 2012)

Check Interactions

No interactions were found for the drugs you selected.

You searched for interactions between the following drugs :

- **Ibuprofen Capsules**
- **Naproxen Tablets**

[Add or Delete Drugs](#)

[Start Over with a New List of Drugs](#)

(**Note:** Not all drug interactions are known or reported in the literature, and new drug interactions are continually being reported. This information is provided only for your education and for you to discuss with your personal healthcare provider.)

Figure 2. Results in having “no interactions” (From Drug Digest, 2012)

Check Interactions

Check potential interactions* between two or more drugs (complete instructions below):

Drug

Search Results

- 2-Amino-2-Deoxyglucose
- 2-Dimethyl aminoethanol
- 2-Dimethylaminoethanol
- 24-alpha-ethylcholestanol
- 3-beta,5-alpha-stigmastan-3-ol
- 3TC
- 3TC and AZT
- 3TC and ZDV
- 4% Skin Bleaching Topical Gel

Interaction List

- Aspirin Chewable Tablets
- Coumadin Tablets

☒ Check Interactions with Food and Alcohol

Figure 3. Checking the interaction between Coumadin and Aspirin (From Drug Digest, 2012)

Check Interactions

4 potential interactions were found for the drugs you selected.

You searched for interactions between the following drugs :

- **Aspirin Chewable Tablets**
- **Coumadin Tablets**

[Add or Delete Drugs](#)

[Start Over with a New List of Drugs](#)

(**Note:** Not all drug interactions are known or reported in the literature, and new drug interactions are continually being reported. This information is provided only for your education and for you to discuss with your personal healthcare provider.)

Figure 4. Results in having “potential interactions” (From Drug Digest, 2012)

B. BARCODES

A barcode is a data encoding scheme that allows for fast, accurate, and easy to use data entry without requiring the use of a keyboard (Gao, Prakash & Jagatesan, 2007). The original and most common barcodes are one-dimensional. Information can be read by scanning it with a hardware device such as a barcode scanner. The ability for a barcode to accurately and efficiently track products has made it desirable in doing business at speeds not capable by manual data entry systems. Barcodes are popular among many businesses today such as the tracking and monitoring of products and goods, supply chain management, and retail sell-and-buy (Gao et al., 2007). Vital roles in these businesses include document storage-and-retrieval, indexing, integrating, tracking, and capturing (Hoke, 2005).

1. What Are Barcodes and Where Did They Come From?

A barcode consists of an arrangement of black vertical lines whose variable widths and spacing encode numbers and letters (Hoke, 2005). Barcodes ease data input for hardware devices and software applications, as alphanumeric symbols are more difficult to read (Hoke, 2005). The barcode was invented by graduate student's Joseph Woodland and Bernard Silver in 1948, but it was not until approximately 25 years later that Woodland developed the linear barcode, which made it the universally accepted standard, especially among grocery stores (Hoke, 2005). Once the barcoded information is captured by the software, the data's use is then determined by rules that are built into the software.

2. How Do Barcodes Work?

To read a barcode, laser beams are used to measure the width and placement of the black lines (Hoke, 2005). The bright light-bar in the scanner conveys the bar pattern such as the black and white lines to a software application, which distinguishes it from anything else on a page (Hoke, 2005). The data use is then determined once the software captures the barcode information as well as the guidelines built into the software (Hoke, 2005). An

example of the most elementary version is known as the patch code. This patch code was recognized by earlier scanners as a unique identifier that contained particular instructions (Hoke, 2005). The resolution of barcode printers and scanners, which printed the barcode image that would be scanned, improved with the ability to print more sophisticated material (Hoke, 2005). While scanners advanced in technology, developers began were able to create more sophisticated instructions encoding schemes into the barcodes (Hoke, 2005). Throughout this improvement process, barcodes began to associate with a serial number and distinguish the beginning and end of a barcode by means of a checksum that barcode writers added (Hoke, 2005). Another improvement was launching workflows by, for example, telling capture software to send an image to a particular department (Hoke, 2005).

Software advancement made significant contributions such as increasing the ease of scanned image retrieval through database population and recognizing matches by signaling an error if a beginning and end of a single barcode did not exist simultaneously (Hoke, 2005). Today, barcodes can accept encode letters along with numbers, and some barcodes have accepted, including “special” symbols characters, such as a dollar signs (Hoke, 2005). With these improvements, information such as name, address, and phone number as well as other important information can be extracted stored from in barcode forms (Hoke, 2005). The downfall to the original one-dimensional barcode is that it can only handle up to approximately 20 digits (Denso-Wave Incorporated, 2012).

C. TWO-DIMENSIONAL BAR CODES

To meet the growing need for barcodes to encode alphanumeric data including numbers, letters, and even punctuation marks, two-dimensional bar codes were invented (Gao et al., 2007). Software advancements have made significant contributions, such as increasing the ease of scanned image retrieval through database population and recognizing matches by signaling an error if a beginning and end of a single barcode did not exist simultaneously (Hoke, 2005).

Today, there are two-dimensional barcodes that can encode letters along with numbers, including “special” characters, such as a dollar sign (Hoke, 2005). With these improvements, information such as name, address, and phone number as well as other important information can be stored in barcode form (Hoke, 2005).

Further, the two-dimensional symbol was a response to an increased demand to store more arbitrary information in general, supporting more character types, and the ability to be produced into a smaller symbol (Denso-Wave Incorporated, 2012). The two-dimensional symbol technology is capable of holding larger amounts of information with the potential to go beyond just tracking products. Getting to this point required trial and error in which increased number of barcode digits or layouts of multiple bar codes did not meet the desired expectations (Denso-Wave Incorporated, 2012). The two-dimensional barcode evolved from the multiple bar code layout to the stacked bar code type then finally to the matrix type (see Figure 5).



Figure 5. Evolvement of the two-dimensional barcode (From Denso-Wave, 2012)

Over the years, two-dimensional codes have steadily increased in popularity and usage for the following reasons: the speed and accuracy at which it can access data, its superior functionality characteristics, and the possibilities in which it can be used to connect people through mobile devices (Denso-Wave Incorporated, 2012). There are almost 50 types of two-dimensional code

representations (Lehan, 2011), but the two most well-known from the matrix type are Data Matrix (ISO/IEC 16022:2000) and Quick Response (QR) code ISO/IEC 18004:2000). The QR code, however, has become the buzz word for two-dimensional code representation especially among the mobile device users, and its technical abilities draw users and developers to its use. See Table 2 for a comparison of the features of the QR code to other similar two-dimensional codes.





		QR Code	PDF417	DataMatrix	Maxi Code
					
Developer(country)		DENSO(Japan)	Symbol Technologies (USA)	RVSI Acuity CiMatrix (USA)	UPS (USA)
Type		Matrix	Stacked Bar Code	Matrix	Matrix
Data capacity	Numeric	7,089	2,710	3,116	138
	Alphanumeric	4,296	1,850	2,355	93
	Binary	2,953	1,018	1,556	
	Kanji	1,817	554	778	
Main features		Large capacity, small printout size High speed scan	Large capacity	Small printout size	High speed scan
Main usages		All categories	OA	FA	Logistics
Standardization		AIM International JIS ISO	AIM International ISO	AIM International ISO	AIM International ISO

Table 2. Comparison of the QR code to similar two-dimensional codes (From Denso-Wave, 2012)

D. QR CODE

The QR code, because of its ubiquity and popularity among smartphone users, is a viable candidate to replace the one-dimensional barcodes currently

used to store the NDC number. What makes it the best two-dimensional choice, other than its ubiquity and popularity, is its flexibility of use and its data storage capacity.

1. History of QR Code

In 1994, a Japanese owned company named Denso-Wave created the QR code for use during the vehicle manufacturing process in order to track vehicles. It was designed to be easily interpreted by scanner equipment. A patent that covers the QR code technology is currently held by Denso-Wave, but to encourage adoption, it allows anyone to use it license-free (Lehan, 2011).

2. Features of the QR Code

The QR code is designed as a two-dimensional matrix code that unlike the original one-dimensional barcode containing only vertical lines, contains both vertical and horizontal lines of information that can be scanned more easily. The data area in the QR code is constructed by units called code words; each is equal to eight bits (Denso-Wave Incorporated, 2012).

One of the distinguishing features of a QR code is its ability to store up to several hundred times more information than the original bar codes, which could only store a maximum of 20 digits (Denso-Wave Incorporated, 2012). There can be up to 7,089 numeric characters; 4,296 alphanumeric characters; 2,953 bytes of binary data; 1,817 Kanji, full-width Kana characters that can be also encoded in a single QR code (Denso-Wave Incorporated, 2012) (see Figure 6).

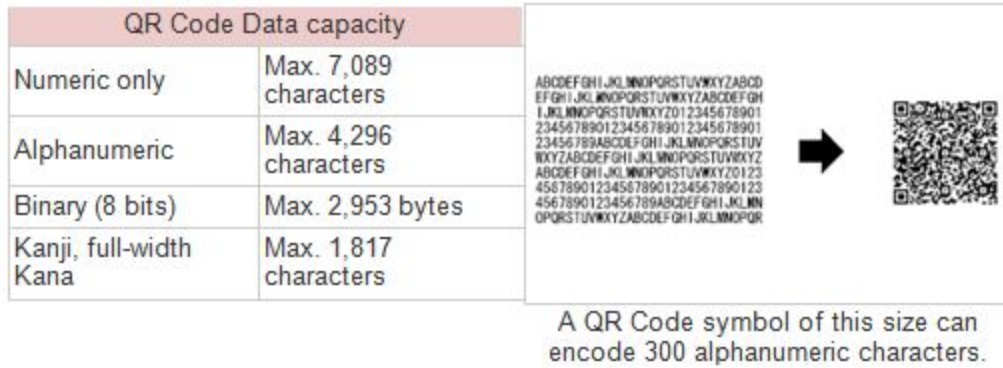


Figure 6. QR code data capacity (From Denso-Wave, 2012)

A QR code can be one-tenth the size of a traditional barcode (see Figure 7) and still be capable of encoding the same amount of data as the barcode.



Figure 7. Traditional barcode (From Denso-Wave, 2012)

Storing information in two-dimension allows QR codes to be capable of omnidirectional, high speed reading (Denso-Wave Incorporated, 2012). This is accomplished through position detection patterns that are located at the three corners of the symbol (see Figure 8) (Denso-Wave Incorporated, 2012).

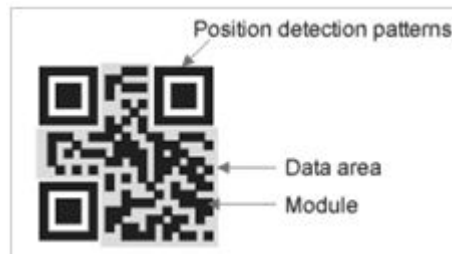


Figure 8. Position detection patterns (From Denso-Wave, 2012)

Another unique aspect of QR codes is its ability to be divided in up to 16 separate symbols (Denso-Wave Incorporated, 2012). For example, one can take a QR code that may be too large to print on a narrow area and condense it down to up to 16 individuals QR codes that can be read the same as one larger one (see e.g., Figure 9). Those same multiple QR codes can be recombined into a single QR code.



Figure 9. QR codes divided (From Denso-Wave, 2012)

a. Error Correction

There are many surfaces onto which a QR code can be printed and still read, but the most popular surface is paper. However, there are concerns about the readability of a QR code if the paper on which it is printed is damaged or occluded. QR codes support a Reed-Solomon error correction code to allow it to be still readable (see Figure 10) (Denso-Wave Incorporated, 2012). To correct code word using a Reed-Solomon code requires twice the amount of code words. For example, if 50 code words of QR code have been damaged, correcting it will require 100 Reed-Solomon encoded code words. For this example, the combination of the QR code and the Reed-Solomon code adds up to a total of 200 code words (100 QR code+100 Reed-Solomon), in which 50 can be corrected (Denso-Wave Incorporated, 2012). This means that for this example 25 percent can be corrected. It is important to note again that 25 percent is

considering the total of both the QR code code words and the Reed-Solomon code words, because even the error correcting code words can get damaged.



Figure 10. Damaged QR (From Denso-Wave, 2012)

According to the QR code specifications outline on the Denso-Wave Corporation's website, there are four error correction levels (see Table 3) to choose from ranging from seven percent to a maximum of 30 percent of code words (units of data equaling eight bits) restoration (Denso-Wave Incorporated, 2012). The level of error correction that is chosen is motivated by the environment that it will be deployed in, as well as the code's printed size. An increase in the QR code size (amount of data) means there must be an increase in the correction level (Denso-Wave Incorporated, 2012). Denso-Wave uses a factory as an example of an operating environment where a larger correction level may be needed in case a QR code gets dirty (Denso-Wave Incorporated, 2012). Cleaner environments such as hospitals may require a lower correction level such as the typical 15 percent that allows for a smaller QR code size to be used. The following is an example taken directly from the Denso-Wave website and can be used as a tutorial for symbol version determination:

If there are 100 digits of numerical data, set the data type as "Numeric". Next, specify an error correction level. Then, find the intersecting value (the maximum data capacity) of the data type sequence and the specified error correction level. The value must be 100 or above, but as close to 100 as possible. If the error correction level is M (error correction capability of 15 percent the code size is 29x29 modules, which corresponds to Version 3).

QR Code Error Correction Capability*	
Level L	Approx. 7%
Level M	Approx. 15%
Level Q	Approx. 25%
Level H	Approx. 30%

Table 3. QR code error correction capability (From Denso-Wave, 2012)

3. Standardization and Specification

Standardization and specification is necessary to understand, when it comes to the use of QR codes. Although QR codes are covered by a patent, the Denso Wave Corporation makes the specifications available to the public in order to increase its use and help it gain popularity (Denso-Wave Incorporated, 2012).

a. History of Standardization

The history of the standardization can be seen in Figure 11. This chart depicts the QR code's successful international acceptance in 2000 when it gained approval by the International Standard Organization (ISO) (Denso-Wave Incorporated, 2012).

QR Code Standardization	
October, 1997	Approved as AIM International (Automatic Identification Manufacturers International) standard (ISS - QR Code)
March, 1998	Approved as JEIDA (Japanese Electronic Industry Development Association) standard (JEIDA-55)
January, 1999	Approved as JIS (Japanese Industrial Standards) standard (JIS X 0510)
June, 2000	Approved as ISO international standard (ISO/IEC18004)
November, 2004	Micro QR Code is Approved as JIS (Japanese Industrial Standards) standard (JIS X 0510)

Figure 11. History of QR code standardization (From Denso-Wave, 2012)

b. Obtaining Specification

Since the QR code is established as an ISO standard (ISO/IEC 18004), the actual specifications can be purchased from ISO's website at <http://www.iso.ch/iso/en/prods-services/ISOstore/store.html> by entering 18004 in the "Search and ISO Catalogue" field (Denso-Wave Incorporated, 2012). Denso Wave provides an outline of these specifications on its website. The outline describes the symbol size, the character amounts that can be stored, and the percentage of the code that can be restored during the error correction process (see Figure 12). Another useful specification on the outline is the "structured append," which is a feature that allows the QR code to be divided into multiple data areas (QR-Server, 2012). This allows for printing in a narrow area (QR-Server, 2012). Another advantage to the "structured append" is the ability to store information in multiple QR code symbols and then reconstruct it into a single string (QR-Server, 2012). The scanning sequence is also inconsequential (QR-Server, 2012).

Symbol size	21 × 21 - 177 × 177 modules (size grows by 4 modules/side)	
Type & Amount of Data (Mixed use is possible.)	Numeric	Max. 7,089 characters
	Alphanumeric	Max. 4,296 characters
	8-bit bytes (binary)	Max. 2,953 characters
	Kanji	Max. 1,817 characters
Error correction (data restoration)	Level L	Approx. 7% of code words can be restored.
	Level M	Approx. 15% of code words can be restored.
	Level Q	Approx. 25% of code words can be restored.
	Level H	Approx. 30% of code words can be restored.
Structured append	Max. 16 symbols (printing in a narrow area etc.)	

Figure 12. ISO/IEC 18004 QR code standard (From Denso-Wave, 2012)

4. Configuration

The QR code requires special software for creation and a printer capable of producing the symbol created (Denso-Wave Incorporated, 2012). A device to scan the software is also required for readability. The scanning device can include a range of commercial barcode scanners with two-dimensional scanning capabilities or something as simple as a cellular phone with an appropriate OCR application. For this thesis, the chosen scanning devices will be mobile devices and their applications for reading the two-dimensional code. However, it is important to note that the size (area) of the QR code can determine readability.

5. Determining Code Size Usage

Deciding what size QR code to use is determined by several factors. These factors include symbol version, which contains data capacity, character type (previously discussed) and error correction, while module size consists of both printer and scanner resolution (Denso-Wave Incorporated, 2012). Each one contributes to a QR code's size (see Figure 13).

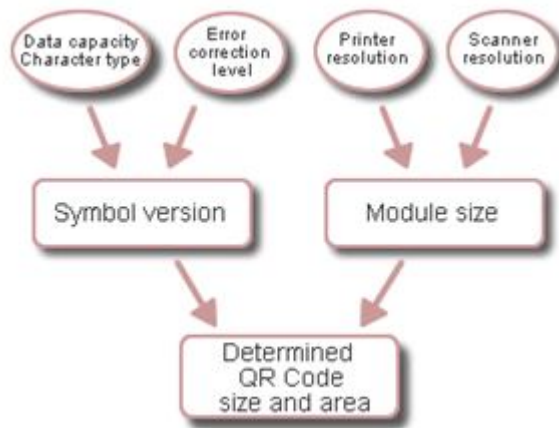


Figure 13. QR code size decision factor (From Denso-Wave, 2012)

There are 40 versions of the QR code and each one has a different number of modules (dots) and a different module configuration. Each version increases by four additional modules on each side (Barcode Library, 2010). For

example, version 1 contains 21 modules on each side, version 2 contains 25 modules on each side, and version 40 contains 177 modules on each side (see Figure 14).

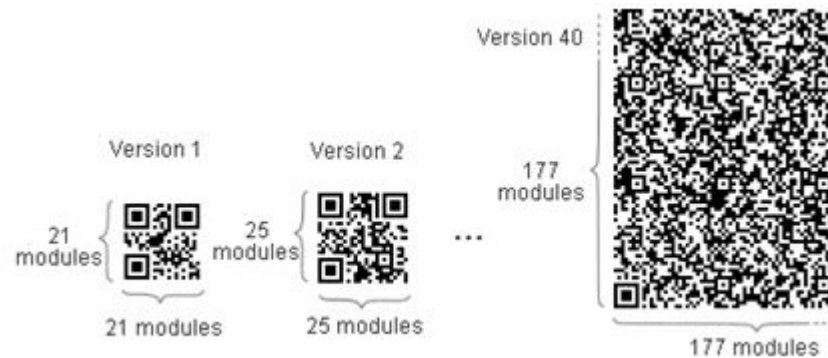


Figure 14. QR code versions (From Denso-Wave, 2012)

The “Versions and Maximum Data” table (see Appendix) shows the maximum data capacity for each of the QR code symbol versions. This maximum data contains the maximum amount of data, character type, and error correction level that a QR code can withstand. For example, (see Figure 14) shows that the maximum data that can be contained in version 1 must fit into 21x21 modules, or it will be increased to the next version and continue until it has reached the version 40 maximum of 177x177 modules (Denso-Wave Incorporated, 2012).

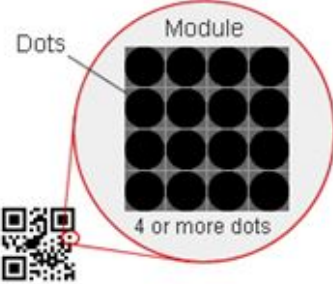
6. Module Size

Setting the module size depends on the QR code area size of the module that will be printed (see Figure 15). This takes place after the symbol version has been determined. Generally, the larger a QR code is, the easier it is to read, but naturally will consume more physical space. This is something necessary to consider when deciding where or on what to place the QR code.



Figure 15. Setting the module size (From Denso-Wave, 2012)

Printers are another limiting factor when considering QR code size. The number of dots in the printer head (resolution)-determines the module size of a standard thermal transfer/direct thermal printer (Denso-Wave Incorporated, 2012). An example of this would be if a head density is 360 dpi and is made up of four dots, then the module size would be 0.28mm² (see Figure 16). According to Denso-Wave, 2012, “increasing the number of dots improves printing quality, eliminates printing width or paper feed speed fluctuations, distortion of axis, blurring, etc..., and enables more stable operations.” To achieve stable operations, Denso-Wave recommends that at least four or more dots make up a module (Denso-Wave Incorporated, 2012).



Printer and module size				
Printer	Head density	4-dot configuration	5-dot configuration	6-dot configuration
Laser	600dpi (24dot/mm)	0.17mm	0.21mm	0.25mm
	360dpi (14dot/mm)	0.28mm	0.35mm	0.42mm
Thermal	300dpi (12dot/mm)	0.33mm	0.42mm	0.5mm
	200dpi (8dot/mm)	0.5mm	0.63mm	0.75mm

Figure 16. Printer and module size (From Denso-Wave, 2012)

Similarly, the resolution of QR code readers is also a factor to consider when it comes to QR code module size. There is a readable module size limit for each scanner and is represented by the scanner's resolution (Denso-Wave Incorporated, 2012). The example that Denso-Wave (2012) uses for this is a QR code symbol being printed with a 600dpi, four dot printer, resulting in a 0.17mm module size. In this case, a the type of scanner required to read the QR code Symbol is one that has a resolution less than a 0.17mm (see Figure 17).

High resolution type	<u>AT10Q-HM</u>	0.167mm
	<u>GT15Q series(for US/for EU ASIA)</u>	
Standard type	<u>BHT-760QWBG-CE</u>	0.25mm
	<u>BHT-600Q series</u>	
	<u>AT10Q-SM</u>	
Camera type	<u>QD20</u>	Variable according to lens
Decode software	<u>QRdeCODE</u>	Variable according to iPhone

Figure 17. Scanner types (From Denso-Wave, 2012)

7. Code Area

Once the symbol version and the module size are determined, the code area can be determined. There needs to be a clear margin area around the actual code where nothing should be printed (Denso-Wave Incorporated, 2012). This clear area must be four or more modules wide around it (see Figure 18) (Denso-Wave Incorporated, 2012).

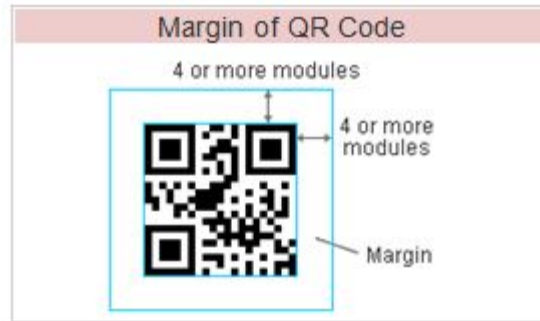


Figure 18. Margin of QR code (From Denso-Wave, 2012)

Calculating the QR code area must be done in order to determine the actual size of the QR code symbol. To calculate the code area, Denso-Wave, 2012 recommends the following five applicable steps using an example of creating a QR code to encode 50 alphanumeric characters that results in a QR code area of 9.398mm²:

- Specify the error correction level as the standard 'M'.
- Obtain a version from the Version and maximum data capacity table (find the intersection of alphanumeric characters and Level M). Version 3 capable of storing 50 or more characters. (Version 2 with Level M holds only 38 characters).
- Use a printer with 400 dpi resolution. 0.254 mm when printed with 4-dot configuration. (Equation: $25.4 \text{ mm/inch} \div 400 \text{ dpi} \times 4 \text{ dots/module} = 0.254 \text{ mm/module}$)
- Version 3 = 29 modules, therefore, the size of QR code is 29 modules \times 0.254 mm/module = 7.366 mm.
- Secure a four-module wide margin. $7.366\text{mm} + 0.254\text{mm/module} \times \text{eight modules} = 9.398\text{mm}$

8. Current Mobile and QR Code Industry Usage

Research has revealed that smartphone usage is increasing yearly and more people are using these devices to access data. In 2010, there were 302.6 million smartphones shipped out around the world by smartphone vendors (Yeh & Fontenelle, 2012). This is a 74.4 percent increase from the number of smartphones that were shipped out by vendors in 2009 (Yeh & Fontenelle, 2012). Mobile users worldwide are becoming increasingly aware of QR codes

and the benefits of scanning them to promptly gain access to information. In 2011, there were 14 million mobile users in the United States alone who scanned a QR code on their mobile device (comScore, 2011). At this time, the dominant age group most likely to scan a QR code was 18-34, which represented 53.4 percent of the population, while 60.5 percent of scanners were male (comScore, 2011). Of this population, ages 18–24 were 36 percent more likely to scan than the average (comScore, 2011). However, all ages and genders are scanning QR codes (see Table 4). It was also found that QR codes located on magazines/newspapers as well as product packages (see Table 4) were more likely to be scanned (comScore, 2011).

Demographic Profile QR Code* Scanning Audience June 2011 Total Mobile Audience U.S. Age 13+ Source: comScore MobiLens 			
	QR Code Audience (000)	% of QR Code Audience	Index**
Total Audience: 13+ yrs old	14,452	100.0%	100
Gender:			
Male	8,743	60.5%	125
Female	5,709	39.5%	76
Age:			
Age: 13-17	1,076	7.4%	108
Age: 18-24	2,402	16.6%	136
Age: 25-34	5,317	36.8%	211
Age: 35-44	2,827	19.6%	117
Age: 45-54	1,798	12.4%	68
Age: 55-64	594	4.1%	28
Age: 65+	437	3.0%	22
Income:			
Income: <\$25k	1,193	8.3%	54
Income: \$25k to <\$50k	2,597	18.0%	79
Income: \$50k to <\$75k	2,756	19.1%	96
Income: \$75k to <\$100k	2,689	18.6%	125
Income: \$100k+	5,217	36.1%	134

Table 4. Demographic profile for QR code scanners (From comScore, 2011)

Currently, QR codes are largely used for marketing. This holds true for healthcare and non-healthcare industries alike. These similarities can be seen in research for all aspects of the industry. Healthcaresuccess, 2012 provides the following examples of what QR codes are being use on and with:

- Billboards and outdoor signage
- Brochures, flyers, newsletters, coupons
- Community event display tables (health fair, chamber functions)
- Custom logo adaptations
- Customer/patient feedback and satisfaction survey on receipts and checkout papers
- Dental office ceiling or similar unexpected site
- Directional signs, maps, event info boards
- Email (signature block), business cards, name tags
- Facebook, LinkedIn, YouTube or other social media connection
- Inside signs, posters, labels
- Journal and publication articles
- Launch a podcast
- Links to patient education or how-to videos
- Online advertisements or special Web pages
- Print advertising (newspapers, magazines, direct mail)
- Product data, specs or user reviews on displays and/or labels
- Product reorder or service recall schedule
- RSVP on event direct mail
- T-shirts, clothing
- Windows, showcase, reception area displays

The healthcare industry differs in the way that hospitals, clinics, and doctor's offices are using QR codes other than just for marketing surveys and patient education/how to information. The healthcare industry has been using QR codes to market a way for patients to have better access to appointments and become more familiar with their doctors and hospitals. The Nebraska Medical Center is currently using QR codes to link patients to an introduction of the

physician that they will be using as well as provide facility tours where they will be treated (Dolan, 2011). This is very beneficial when it comes to specialty appointments or procedures. Regional Health Services of Athens, GA is using QR codes to allow women to access appointments for mammograms, which means that they have the ability to see what dates and times are available and immediately request to be given the available opening (Dolan, 2011). The goal is to provide a proactive way for women to get their mammogram completed (Dolan, 2011). Patient testimonials are another useful aspect of QR codes and work well for the labor and delivery ward at Poudre Valley Health System in Fort Collins, CO. This provides easy access for expecting mothers to hear testimonials from former patients of the Poudre Valley Health System as well as give testimonials after their own experiences.

EHRs, which will be discussed later in more detail, are another use of QR codes. This has not been on the market long and there are still skeptics about the concept. A company known as MD MedicStats, LLC is marketing a product that offers quick access to a person's medical record. This plastic wallet card and key chain card has a QR code that links straight to the personal medical record after being scanned by a smartphone. The electronic medical record will also provide a list of drugs that a patient is currently taken. The only barrier that the company believes is currently standing in the way is consumer adoption (Twiddy, 2001).

E. NATIONAL DRUG CODE

1. National Drug Code History

The National Drug Code, an 11 digit drug identifier (Berman, 2004), was created in 1969 by the FDA so that drug manufacturers, distributors, hospitals, insurance companies, and the government could have an identification system that automatically processes drug data using a computer (Rodgers, 2012). This automatize computer process would increase efficiency and accuracy resulting in fewer human errors in drug distribution. It began as a voluntary means for

manufacturers to identify drugs, but in 1972 the FDA made it mandatory for all prescription and over the counter drugs to obtain a “labeler code” and place the NDC on drug packages (Rodgers, 2012). It is important to note that the NDC is only a number and not a barcode. When the NDC became mandatory in 1972, barcodes were not required to be associated with the NDC number. Each drug had only the number associated with it whether a barcode existed or not. Obviously, if a barcode did not exist then the number would have to be recorded.

After the Uniform Grocery Code Council (UGCC), now known as GS1 U.S., introduced the Universal Product Code (UPC) it became a standard product code and barcode symbolism for all products sold at chain stores using a check-out counter (Rodgers, 2012). This led to mandating that these chain stores also place a UPC inventory number on all over-the-counter medications. The success of this automated manufacturing system prompted the FDA to express interest in having this 12 digit, one-dimensional, linear barcode placed on all drugs manufactured and sold in the U.S. As a result, the UGCC reserved the number three at the beginning of the UPC as a pre-pending digit for all drug companies and a standard UPC checksum at the end (Rodgers, 2012).

A 1999 report from the Instituted of Medicine (IOM) titled *To Err is Human: Building a Safer Health System* led to an effort to reduce medication errors (21 CFR, 2003; M2 Communications Ltd, 2004). For the next few years, these efforts eventually steered the FDA into mandating that all drug manufacturers use a standardized bar code label that is machine readable and contains the NDC. This was to be placed on drug product containers as well as the single unit containers that are used by hospitals for single dose distribution (21 CFR, 2003). In addition to reducing medical errors by monitoring ADEs, the National Drug Directory would aid in the efforts to implement product recalls, counter bioterrorism attacks by identifying sources of drugs, and address drug related emergencies.

2. National Drug Code Anatomy

The NDC is divided into the following three segments: the FDA labeler code, the product code, and the package code. The FDA labeler code, issued by the FDA, is assigned to a manufacturer, packager, or company that repackages a drug. The product code contains drug information such as strength and dosage and is assigned by the labeler. Once it is assigned, it must be registered with the FDA. The last segment of the NDC is the package size that is associated with the actual package size or package grouping of the drug (Rodgers, 2012).

The labeler code contains either a four or five digit code number. However, the code number ultimately results in five digits after a zero is added to the four digit code numbers chosen by manufacturers (Rodgers, 2012). By only having four digits, the FDA would be limited to 10,000 labeler codes, but by allowing a five digit code number, the amount of labeler codes available could increase to 100,000 (Rodgers, 2012). The only issue with requiring a five digit code number is that manufacturers could end up generating the same code for two different products (Rodgers, 2012). This problem was solved by not issuing codes 1000–9,999 and placing a zero in front of the four digit codes to make them a five digit code (Rodgers, 2012).

Manufactures have a choice between two different formats for the product and packing code. Manufacturers can choose a three or four digit product code and a one or two digit packaging code. However, the entire NDC must still equal 11 digits. If the manufacturer chooses a three digit product code and a two digit package code, then a zero will be added to the left of the product code thus giving it a 5-3-2 format with the zero making it a 5-4-2 format equaling 11 digits. If a 4 digit product code is chosen with a one digit packaging code, then a zero will be added to the left of the packaging code thus giving it a 5-4-1 format with the zero in the packaging code making it a 5-4-2 format equaling 11 digits.

The format of a drug's package code is unique to each manufacturer. For example, a manufacturer may choose package code values of one, two, and

three to represent prescription bottle counts of 30, 60, and 90 while other manufacturers may choose 30, 60, and 90 as the actual packaging code numbers to represent the 30, 60, and 90 count bottles (Rodgers, 2012). This could be confusing for whomever is tracking bottle counts. The capacity that QR codes allow would provide a way to standardize the bottle counts for every manufacturer.

3. National Drug Code Directory

The NDC Directory contains a list of all drugs that are distributed in the United States. According to the FDA (2012) registered pharmacies are required to identify their drugs to the FDA. Unless a waiver is granted, this information must now (since June 2009) be submitted electronically via a system known as eLIST (Rodgers, 2012). This includes drugs that are processed, compounded, prepared, propagated, or manufactured for commercial distribution (FDA, 2009).

As part of the listing in the NDC Directory, the FDA publishes the NDC numbers and information that are submitted by pharmacies. This is updated every Monday by the FDA. The pharmacies are required to update their drug listing data in June and December (Rodgers, 2012). The FDA provides a list on its website (FDA.gov) to help guide pharmacies on the NDC requirements.

F. ELECTRONIC HEALTH RECORDS AND QR CODES

The idea of an electronic health record (EHR) or an electronic medical record (EMR) was created over 50 years ago to provide clinicians timely and efficient access to their patients' full health history (Waegemann, 2003). In order to promote the adoption of EHRs in the U.S., the U.S. Health Information Technology for Economic and Clinical Health (HITECH) Act was signed into law (Charles, Furukawa, King, & Patel, 2013). A National Center for Health Statistics (NCHS) data brief published in December 2012 showed that 72 percent of physicians in the United States now use an EMR system (Hing & Hsiao, 2012). A physician workflow study conducted in 2011 showed that 84 percent of physicians that have adopted an EHR reported being somewhat or very satisfied

with their system (Jamoom, Beatty, Bercovitz, Woodwell, Palso, & Rechtsteiner, 2012). An Office of the National Coordinator for Health Information Technology (ONC) data brief showed that as of December 2012 the adoption of EHR systems among hospitals is at 85 percent (Charles et al., 2013). For the purposes of this paper the term Personal Health Record (PHR) is also synonymous with an EHR.

1. EHR and EMR Defined

The National Alliance for Health Information Technology (NAHIT) defines an electronic health record as “an electronic record of health-related information on an individual that conforms to nationally recognized interoperability standards and that can be created, managed, and consulted by authorized clinicians and staff across more than one healthcare organization” (Amatayakul, 2009). The office of the National Coordinator for Health Information Technology (ONC) stated that EHRs are “built to share information with other healthcare providers, such as laboratories and specialists, so they contain information from all the clinicians involved in the patient’s care” (Garrett & Seidman, 2011).

The NAHIT defines an electronic medical record as an electronic record of health-related information on an individual that can be created, gathered, managed, and consulted by authorized clinicians and staff within one healthcare organization (Amatayakul, 2009). Another definition of an EMR is “a computerized system that contains a patient’s long-term legal health record generated by encounters at one particular medical practice” (Meinert & Peterson, 2009). The data located within the EMR is a legal record of what happened to the patient while at that healthcare organization and is the property of that healthcare organization (Garets & Davis 2006).

2. EHR Versus EMR Comparison

The main difference between an EMR and an EHR is the accessibility and location of the record. EMRs are local to the record. NAHIT states, “The principal difference between an EMR and an EHR is the ability to exchange

information interoperably” (Amatayakul, 2009). The term “medical” in EMR solely related to the clinicians that diagnosed and treated their patients, and that information stayed solely in that clinician’s organization (Garrett & Seidman, 2011). The word “health” in the EHR signifies the overall health of the patient vice the patient’s medical record (Garrett & Seidman, 2011). Because the EHR covers overall health of the patient is imperative that access is available to all individuals that treat the patient whether it is in one healthcare organization or another. With that said, interoperability is the main difference between an EMR and an EHR (Amatayakul, 2009).

The benefits of an EMR is that it allows the clinician at the healthcare organization at which the EMR is located to retract the patient’s data and health over time. It also allows the clinician to track when the patient is due for certain checkups or screenings. Additional benefits of EMR technology includes “improved quality of patient care, more efficient healthcare workflows, and reduce costs” (Thompson, Osheroff, Classen & Sittig, 2007). Another benefit of an EMR is that a clinician can track the patient over time to see how the patient is doing. For example blood pressure monitoring or diabetes management. The ability to monitor and help improve the overall care of the patient within the healthcare organization that the EMR is located is probably the greatest benefit that an EMR provides (Garrett & Seidman, 2011). Studies have shown that the use of an EMR can create continuous quality improvements for diabetes care (Devkota, Reichart, Ambrecht, & Smith, 2013).

A weakness of an EMR is that the data located within the EMR remains at the local healthcare organization. The data located within the EMR does not travel easily outside that local healthcare organization (Garrett & Seidman, 2011). If a patient would like a clinician at another facility to see what is inside their EMR, then that patient would have to have his or her record printed out on paper or burned on a CD to be taken to the other healthcare organization. In that sense and EMR is no much better than a paper record when it has to be transferred to another healthcare organization (Garrett & Seidman, 2011).

The EHR has many of the benefits that an EMR has with a few additional ones. Perhaps the most important benefit of an EHR is that information in it can be seen by all clinicians that are involved in the patient's care (Garrett & Seidman, 2011). EHRs are designed to focus on the overall health and care of the patient, regardless of where the care took place. This care information by design can thus follow the patient across the state, country, from hospitals, to nursing homes (Garrett & Seidman, 2011). Another key benefit of EHRs is that ideally all of the patients' healthcare providers should have access to the most up-to-date information regarding the patient. In addition, if a patient is highly engaged in his or her health, that patient may be able to login to a website to view the current status of a test that was administered. A physician workflow study conducted in 2011 showed that about 75 percent of clinicians that adopted EHR systems stated that the EHR system resulted in enhanced patient care (Jamoom et al., 2012) (see Figure 19).

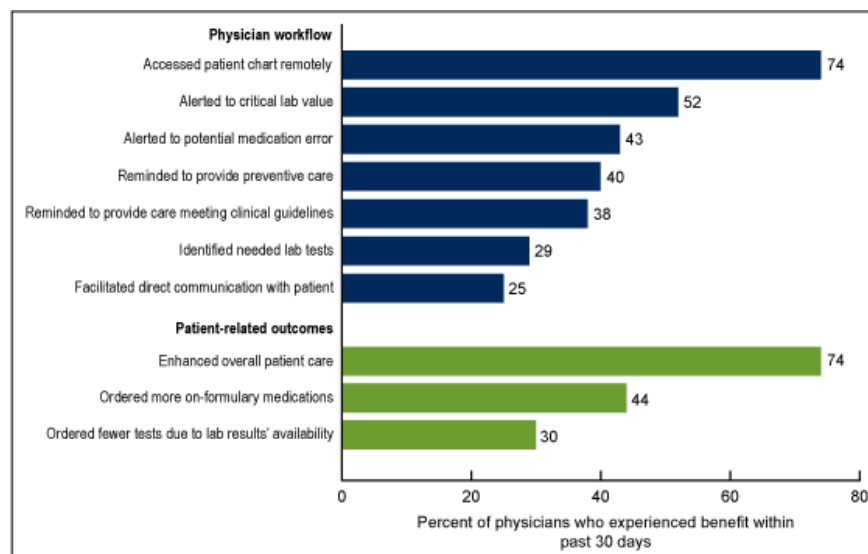


Figure 19. Physician workflow study (From CDC/NCHS, 2011).

3. EHR Standards and Adoption

The heart of the issue when discussing EHRs is interoperability, and standards. Interoperability enables different information systems to exchange

information and to use the information that has been exchanged (Melvin, 2009). Without interoperability, a patient's EHR cannot move with them from clinician to clinician, regardless of where it originated. Figure 20 shows that interoperability can be achieved on many levels, a high level of interoperability means that the two systems: a pharmacy management system and a radiology system can talk to each other in a format that both understand. The lower the level of interoperability, the more unstructured the data becomes (Melvin, 2009). The goal is to have the level of interoperability among EHRs lies somewhere between levels three and four.

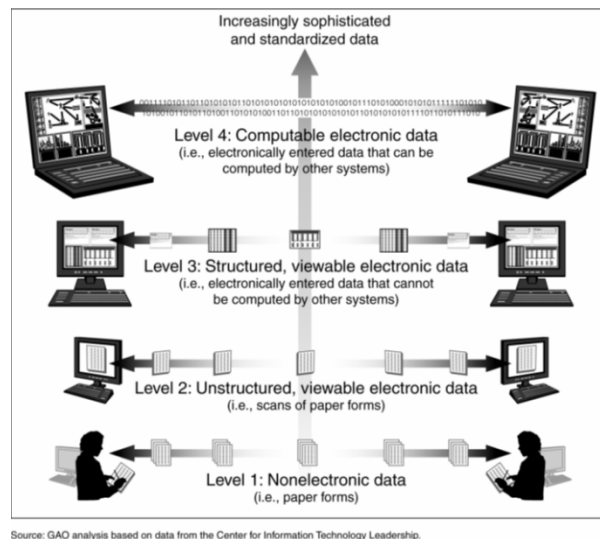


Figure 20. Interoperability levels (From Melvin, 2009)

Another motivation for the creation of the HITECH Act was to provide a set of standards that govern the use of EHR's (Fridsma, 2012). The HITECH Act program focuses on attaining meaningful use of EHRs as a way to improve health system performance through the adoption of EHRs, and the development of security and private pathways for exchanging health information (Blumenthal, 2010). Meaningful use is a set of standards defined by the Centers for Medicare and Medicaid Services (CMS) that govern the use of EHRs (Fridsma, 2012).

Meaningful use uses EHR technology to improve quality, engage patients, improve care coordination, and to maintain privacy and security of patient health information (HealthIT.gov, 2013).

An agreed upon list of standards is imperative in order to obtain the level of interoperability and IT management needed for a successful EHR. These standards can range from technical areas to medical. For example, a technical standard would be a list of agreed upon file types. A medical standard such as common vocabulary terms and codes would help to determine how information is documented for diagnoses and procedures (Melvin, 2009). Messaging standards help to establish the order and sequence of data during transmission and help to provide for a uniform electronic exchange of data (Melvin, V. 2009).

The passing of the HITECH Act allowed for standardization and interoperability among EHRs. The HITECH Act fueled initiatives that are looking at ways to establish standardized healthcare vocabularies, and standardized secure protocols (Fridsma, 2012). As these standards are agreed upon by the healthcare community, measures will be put in place to ensure standards compliance (Fridsma, 2012). The consensus of standards and interoperability has helped to fuel the success of the adoption of EHRs in the United States. The adoption percentage of EHRs by both physicians and U.S. non-federal acute care hospitals is very high and rising (see Figures 21 and 22).

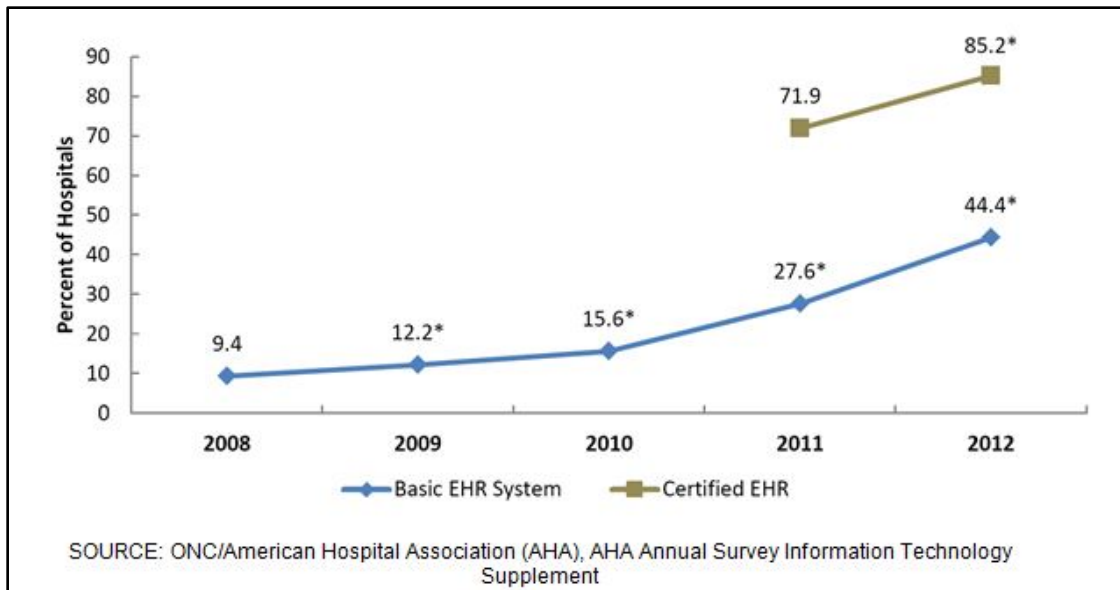
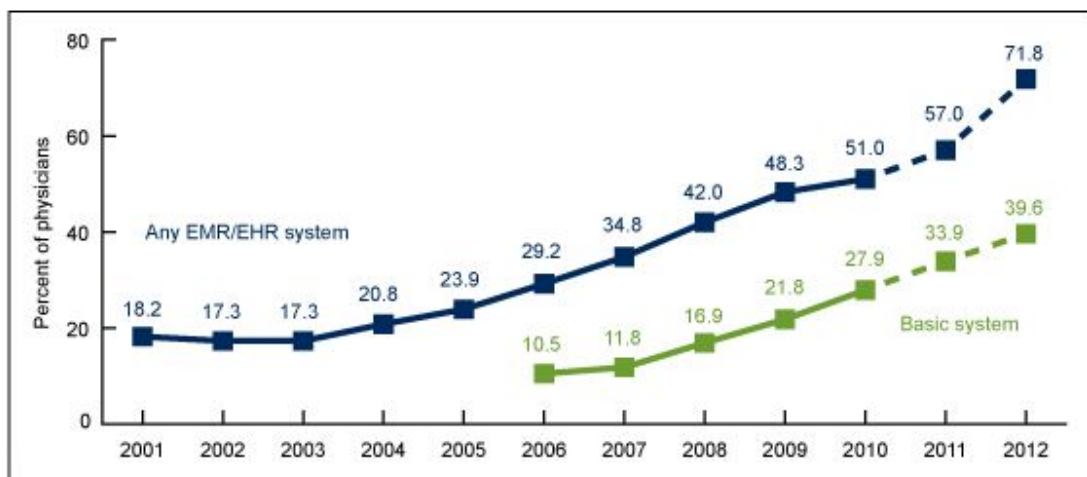


Figure 21. Non-federal acute-care hospitals EHR adoption (From Charles et al., 2013)



SOURCE: CDC/NCHS, National Ambulatory Medical Care Survey, 2001–2012.

Figure 22. Office-based physicians with EMR/EHR systems (Hing & Hsiao, 2012)

As the adoption of EHR systems in the United States continue to grow, more focus needs to be placed on how that data can be accessed by emergency medical personnel. There is a gap in providing immediate, real-time access to EHRs for all interested parties, especially emergency medical personnel, in cases where the patient may be unconscious or unable to communicate their

health history to the EMT (Langford & McCoy, 2013). This is currently a hard problem because currently there is no successful, cost effective solution for providing EMTs access to the patient's EHR (Langford & McCoy, 2013). EMTs have to make assumptions about the patient's current medical history based on the patient's current condition and on any medications on the patient's person or in his or her residence.

4. Current Usages of EHRs and QR Codes

Access to patient medical information by emergency workers in emergency situations can mean the difference of life or death for the patient. Access to that information can be provided in many ways, such as a medical ID bracelet, and emergency card, or via QR code. These are just some of the ways that an emergency worker can get access to that information. There have always been numerous ways for patient to store his or her critical health information (medications and allergies), but few that utilize the QR code in technology. The idea to use QR codes to provide access to medical information is not new. Currently, there are a few companies that are looking into ways to use QR codes in emergency medical situations.

Marin County, California is currently partnering with Lifesquare, Inc. to test the use of QR codes with Emergency Medical Technicians (EMT) and paramedics to instantly view a patient's medical information. The EMTs and paramedics can view the patient's health information, including his or her allergies and medications by using a mobile device by scanning a QR code (From QR to ER, 2013). The QR code encodes a URL to a Web service which stores the patient's health information. The Lifesquare service is currently only available in Marin County, California, and proprietary software needs to be purchased to ensure that the patient information is able to be read both by the EMT and by the hospital (From QR to ER, 2013).

Similarly, the Connectyx Technologies Holdings Group, a company that provides products for the healthcare market, has an online personal health

records system that allows members to store their important medical information online. EMTs are then able to access that information via scanning that QR code with a mobile device. The QR code will then direct the mobile device to a website at which the EMT will input an emergency code unique to the patient (Connectyx Technologies Holdings Group, Inc., 2011).

A U.S. patent application published in February 2013, titled: "Using Quick Response (QR) Code to Authenticate, Access, and Transfer Electronic Medical Record Information" details a system consisting of a computer program, which uses QR codes to identify patients and their medical records (Langford & McCoy, 2013). This system would then authenticate the user via the Web, and provide both patients and healthcare provider's access to a Web-based EMR (Langford & McCoy, 2013). This process consists of the scanning of the patient's QR code, followed by a second scan of the QR code assigned to the particular healthcare facility performing care (Langford & McCoy, 2013). After both QR codes are scanned a user specific identification code and password are required before access to the patient's EHR is granted (Langford & McCoy, 2013). This QR code process requires Web connectivity, and also requires that the patient is available to input his or her credentials in order to grant access to the EHR (Langford & McCoy, 2013).

Another U.S. patent application published in November 2012, titled "Personal Health Record (PHR) ID Card Claiming Priority for 61/48262" details a portable, removable, printable card comprising of a person's name, QR code, and information on how to access the data on the QR code (Bennett, 2012). When scanned, the QR code will reveal the card owner's name, and the emergency information that he or she wants hidden within the code (Bennett, 2012). The QR code also provides for the ability to contain a link to the patient's doctor hospital or EHR (Bennett, 2012). This patent also shows a visual representation of a PHR ID card would look like.

M.D. Medics Stats, LLC offers a service that provides a customizable QR code that can also be scanned with a smart phone. When scanned it takes the

viewer to a website that has the person's medical information (Twiddy, 2011). As with other kind QR solutions access to the patient's medical information requires Web connectivity (Twiddy, 2011). The information available on the website can either be available to any individual who scans the QR code, thus making it public, or it can be only available to those with a unique PIN provided by the patient, thus make it private (Twiddy, 2011).

ERMedStat also provides a QR code solution. When the QR code is scanned, it pulls up medical information, the person's emergency contacts, as well as allergies, medications, and any medication interactions (Harrington, 2012). This information is stored directly on the QR code and does not require Web connectivity. Individuals can update their medical profile by accessing the company's website (Harrington, 2012).

As described in this section, there are numerous patents, and companies that are currently utilizing QR codes in medical environments. In the next chapter will discuss the integration of QR codes, EHRs, and the NDC. A combination of these three technological modifications will provide a greater benefit to patients and clinicians.

III. METHODS FOR IMPLEMENTING QR CODES IN HEALTHCARE

A. PHARMACEUTICAL INDUSTRY

1. Technological Modification to Improve the Efficacy of the National Drug Code (NDC) Carrier

a. Two-dimensional QR Code

Research has indicated that two-dimensional barcodes are capable of holding a larger amount of data compared to one-dimensional barcodes (Denso-Wave Incorporated, 2012). This allows for greater efficacy than the one-dimensional barcode used for just tracking products. Although there are a several two-dimensional barcode options to choose from, the QR code is currently the most popular, because of its success rate in readability and compatibility with scanners that are common among the average smartphone user today. Because of its ability to hold alphanumeric data that includes numbers, letters, and even punctuation marks, the two-dimensional QR code is ideal for placing more information on it than the current NDC barcode. Having the ability to place more beneficial information on a two-dimensional QR code may increase the efficacy of the NDC carrier.

A two-dimensional QR code can replace the current one-dimensional NDC carrier without affecting compatibility with systems that support the original 11 digit identifier. As long as this 11 digit identifying number can be retrieved, the two-dimensional QR code has satisfied the requirements of the FDA for each drug product.

Another factor that supports the QR code being chosen to replace the one-dimensional barcode is its flexibility in size. The QR code has the capability of being produced at a very small physical size without affecting its readability. This is beneficial when manufacturers want to produce single doses of medication and still place the NDC label on each dose. If a bottle or syringe is

so small that placing a one-dimensional barcode on it becomes problematic, a QR code can meet this need, based on its ability to be produce in a very small size and read both vertically and horizontally.

The QR code also contains a very important feature necessary in the healthcare industry: the ability to tolerate some form of damage and not affect the integrity of the information. In the healthcare industry, integrity of information is important for ensuring that patients receive quality care. Since medication bottles are consistently being handled or moved through a process, there is a chance that the label could get damaged. This type of damage to a one-dimensional barcode could cause the information to be lost or lose integrity.

b. Technologies

There are various technologies that must be associated with the creation, use, access, and distribution of QR codes. The creation of the QR code involves software that allows a user to create a code and either input data or add a link that can retrieve data. Anyone can create a QR code for free by searching the term “QR code generator” in any of the common internet search engines. Some of the popular and free QR code generating websites include: www.qrcode.kaywa.com, www.the-qrcode-generator.com, www.qrstuff.com, www.goqr.me, and www.createqrcode.appspot.com. There are step-by-step instructions that allow a user to easily create his or her own QR code for either personal use or business and commercial use. Barcodelib.com offers a large variety of barcode creation software with greater abilities to customize. However, a license for this product must be purchased by the owner. This can be useful for businesses and those who use one-dimensional and two-dimensional barcodes in the commercial sector.

Although smartphones are the most commonly used hardware devices, there are hardware devices that are designed specifically for reading barcodes. These hardware devices are currently being used in the pharmaceutical industry for reading one-dimensional barcodes for the purpose of

tracking medications. These barcode readers that are being sold today have the capabilities of reading both one-dimensional and two-dimensional barcodes. Rx Scan, which offers barcode reading solutions to pharmacies, is one example of a company that provides a pharmacy with the ability to scan both one-dimensional and two-dimensional barcodes.

The company provides software that not only extracts the 11 digit NDC number from the barcode, but allows it to be recognized for the purpose of meeting other pharmaceutical business needs similar to enterprise resource planning (ERP). See Figure 23 for an example of how a NDC labels can be deciphered with a barcode scanner.



Figure 23. Deciphering NDC Barcodes (From RX Scan, 2013)

According to Rx Scan's website (2013), the software that the company provides is capable of extracting 11 digit NDC number to any application. The following are application examples that Rx Scan provides in its website (2013):

- Bedside Scanning Application
- Hospital Information System
- Pharmacy Software Systems
- Patient Billing Systems

- Spreadsheets
- QA reports

c. Example: As-is / To-be

Currently, the NDC is being carried by a one-dimensional barcode that contains that 11 digit number in order to keep track of the manufacturer that it came from, the type of product that it is, and its package size, strength, and dose. This is very beneficial for inventory management, distribution, and product identification by pharmaceutical manufacturers and pharmacies. However, this information serves the very limited purpose mentioned above. The idea of adding more information is limited by the lack of space that is provided by a one-dimensional barcode.

A different type of barcode option, such as a two-dimensional barcode, may be more conducive to the idea of placing other important information about a drug product on a barcode. Improving the efficacy of the NDC carrier can be valuable for reducing ADE's if both patients and providers are able to access pertinent information about a drug. By allowing both the patients and providers to access the right information can create a greater dissemination of the correct drug product to whomever needs it. Disseminating the correct drug product means that a patient provides the correct information to every provider that he or she visits and the provider receives the correct information and makes the precise choice on which drugs to prescribe based on current correct medications that the patient is taking.

If a two-dimensional barcode such as a QR code were present on the prescription bottles, then a patient can use his or her smartphone to read the barcode label to gather the information that will help them become more aware of the drug that he or she is taking. There are many types of smartphone applications that can store a drug product in a virtual medication list and provide patients with

a means to keep track of the drugs that they are taking. Some of these applications have a drug interaction alert that will inform the patient if any of his or her drugs could interact and cause an ADE.

For a patient who does not have a smartphone or does not want to participate in scanning the QR code another option is possible that will allow just the provider to get the proper information. If removable, sticky labels that contain the drug's QR code were placed on the prescription medication bottles, a patient could remove the label and place it on a sheet of paper or in a notebook. When a patient visits a provider or even pharmacy, the patient could give that provider or pharmacist the collection of QR code labels, either one or many, and the provider or pharmacist can scan them and ensure that the right list of medications that the patient is currently taking is properly documented. Another benefit to this is the ability for first responders to quickly and accurately gain medical information about a patient they are treating. This can have great benefits for first responders who may have a non-responsive patient.

d. Assumptions

Assumptions of the technology for QR code implementation can be centered on the hardware used by patients. The smartphone, a mobile device capable of scanning and reading a QR code, is assumed to be the most logical device that a patient can use to extract information from a QR code. An assumption for this thesis is that everyone will have a smartphone in the near future. Without collecting data, the assumption must be considered and taken into consideration. It is also assumed that every pharmacy and provider has a barcode reader capable of reading a two-dimensional code.

It is assumed that smartphone and barcode scanner owners are capable of using and being trained to use software to extract, track, and distribute barcode information from both one-dimensional and two-dimensional barcodes. Another assumption that should be considered is whether or not the idea of replacing the one-dimensional barcode with a two-dimensional barcode

will be widely accepted. If this idea is implemented, it is assumed that the pharmaceutical industry as a whole, along with non FDA approved drugs such as vitamins, will adopt this method. Even if the pharmaceutical industry adopts this method, there is only an assumption that providers and patients will adopt it as well. The key to the success of this implementation is that everyone (pharmaceutical industry, providers, and patients) adopts the idea and utilizes it.

e. *Risks*

The first risk to consider is a financial risk for implementing the QR code in place of the current one-dimensional barcode. In regards to any barcode creation, the risks are very low financially. The reason that there are low financial is because it is relatively inexpensive to create a QR code. When comparing the cost of the current one-dimensional barcode that carries the NDC number that the pharmaceutical industry uses for the recommended QR code, the cost should not change. The only possible cost increase could be that the QR code uses more ink to create, but that can be offset by the ability to create a smaller barcode unlike the one-dimensional barcode.

Another suggestion the keep the financial risk low would be to only provide a QR code with each new drug that is manufactured. Since pharmaceutical hardware devices for scanning and reading barcodes have the ability to read both a one-dimensional and two-dimensional barcode, this will not affect the current drug manufacturing and distribution process since the only need for the barcode is to extract the NDC number. Eventually, the old bottles, once used or thrown away, will become obsolete while all new bottles will contain the QR code.

Durability and performance of the QR code is a risk factor, but the QR standard provides for greater error correction after damage than the standard one-dimensional barcode (Denso-Wave Incorporated, 2012). Wear and tear is always a risk factor when using barcodes. Although it would be logical to choose a durable paper to print barcodes on, a QR code's durability has a lower risk

because of its ability to withstand damage. This is an important factor in its contribution to reducing ADEs since preventing distorting information is also a goal of reducing ADEs. By replacing the one-dimensional barcode with a two-dimensional barcode that is more durable and can acquire more damage without affecting readability, the chances of getting errors from scanning the NDC number and possibly losing the integrity of the information will be at a lower risk.

f. Security and HIPAA Considerations

Security and privacy considerations should never be overlooked when there are any changes to technology in the healthcare industry. Since these only reflect the changing of the barcode carrier and do not contain any personally identifiable information (PII), there are no concerns. At this point, the only information placed within the barcode that is being looked at is the NDC number. The NDC number can be accessed by anyone and there are no HIPAA concerns about the NDC number. The only security concern would relate to an individual tampering with the integrity of the NDC number and changing it. However, this vulnerability is no different than that of the one-dimensional barcode. If there are any security concerns, they would not be any different than those of the current as-is process of the NDC number distribution and its barcode carrier.

2. Benefits of Replacing the National Drug Code (NDC) Carrier with the Two-Dimensional QR Code Modification

a. Positive Benefits

There are many positive benefits that can come from replacing the current NDC carrier with a two-dimensional barcode. First, the risks of losing information from a damaged two-dimensional barcode are lower than the one-dimensional barcode. One of the most important benefits to replacing the one-dimensional barcode with a two-dimensional barcode such as the QR code is the ability for patients to be able to access the information stored on it. This is important because the average smartphone hardware contains picture taking

capabilities that allow a user to capture the image of a barcode. One of the most common barcode reading applications that a user can find by searching for applications on his or her smartphone is the QR code reading application. The benefit of replacing the one-dimensional barcode with a two-dimensional QR code can have many positive effects on the healthcare industry. This is because of a patient's ability to access pertinent information that is stored on a QR code which can be relative to his or her overall wellness.

A positive benefit for providers of all aspects of the healthcare industry is the ability to access that same information at any time. With all the technological advances and new software applications in the medical field, the ability to quickly access information or extract it for the purposes of inputting it into another application can be beneficial. Even if the NDC carrier only contained the NDC number, there are software applications that can read and define that number. The ability to place a drug name and possibly all of its information into a database that contains some form of business intelligence capabilities can be beneficial to provider decision making and health management. With the potential of software applications that exist for the pharmaceutical industry and the technological advances in healthcare, having the ability to quickly scan a barcode is inevitable. Current designs of commercial barcode readers are not convenient and still have static like features. Those which are more portable are more costly than those that are not. Since mobile devices, such as the smartphone, have QR code reading capabilities, they are ideal for the average user who does not own a device dedicated only to reading barcodes. Smartphone are convenient.

An example of the convenience of using a smartphone instead a traditional barcode scanner for extracting pharmaceutical information can be best understood by looking at the trends technological features of different devices were implemented into a mobile phone. Smartphones now have the convenience of using a camera, a laptop, a telephone, a PDA device (schedules, personal planning, and contact information storage), a barcode scanner, and many other

previous hardware devices in one. This has led to more than just convenience, it has allowed for users to use the various devices more frequently and at a quicker rate. This benefit could contribute to decreasing actual work time of employees.

Another example of a benefit that comes from more than just providers being able to access pharmaceutical information quickly is the ability for non-providers who perform tasks related to drug management. Committees that consist of non-providers who are tasked with performing controlled substance inventory audits, such as the Controlled Substance Inventory Board (CSIB) that exist in Navy Medicine. When auditing a large list of drugs, there can be confusion on similar sounding drugs. As a former member of CSIB, the author observed that human error usually accounted for any misplacement of drugs as well as mistakes on the audit forms. These mistakes could have been avoided if technology had existed for the author to quickly scan a barcode and get the correct information.

The overall benefit of using a QR code to encode the NDC is that the two-dimensional barcode is more compatible with today's technologies. Another trend that is noticeable is the increased use of tablets that also have the ability to utilize software applications capable of barcodes. Providers are incorporating tablets into their practice since it is a device that can be conveniently taken to each patient's room. If the tablet already contains barcode reading software, there will be no need to purchase devices specifically for barcode scanning. The benefit that comes from this in medical practice and ADE reduction is if medication bottles contain QR codes with the NDC number, then a patient can bring his or her medication bottles to a doctor visit and get them quickly scanned by a provider. This way, the drugs will already be in the system and can ensure that the provider gets that correct information on the medication that a patient is taking and possibly even the dosage, depending on what information the QR code contains. The provider can also use a software application that will display an alert immediately if any drugs interact or if any anticipated drug prescriptions will interact.

b. Negative Benefits Replacing the One-dimensional Barcode with a QR Code

The authors believe that the challenges of replacing a one-dimensional barcode with a two-dimensional QR code are more in the form of adoption and marketing the new technology. Getting patients, providers, and even non-providers to adopt the new method of tracking drugs and getting information about a drug may be difficult. The important factor of marketing the change will be to know who the target audience is. For example, if there are three different groups such as patients, providers, and non-providers that will be utilizing the new form of technology, then marketing tactics may need to be different for each one. Non-providers may be divided into more than one targeted marketing groups such as those who interact with the pharmaceutical industry and those who interact with the patient such as family members.

c. Assumptions of Positive and Negative Benefits

There are several assumptions of the positive benefits that relate to human behavior predictions. The technical benefits of replacing the one-dimensional barcode with the QR code do not have to be assumed. Most of the assumptions from the positive benefits are related to how people will react to the benefits of using a QR code instead of the current one-dimensional barcode. There is a small assumption that everyone will accept the technical abilities of the QR code. Focusing on any other aspect of using this two-dimensional barcode such as the hardware, software application use, learning time, personal involvement, and understanding of its potential benefits are larger assumptions of human interaction and behavior. This assumption is related to how well users will accept and be involved in the potential benefits of the increase efficacy of the two-dimensional QR code.

Assuming that users do completely adopt every aspect that is required to reach the new barcodes full efficacy, there is still a question on whether or not the benefits of reducing ADEs will be achieved. There is still an

assumption that the complete adoptions of all aspect of QR code usage will directly contribute to reducing ADEs. We leave this as future work.

Full adoption assumes that users accept QR codes as being easily accessible with the right hardware and software. It also assumes that the users will embrace the positive benefits by either utilizing the hardware (smartphone) that they currently own or by acquiring the hardware. If the hardware is owned or acquired, it is assumed that the user will download the software applications necessary to gain the full positive benefits. This software should include both the QR code reading software and any software applications that enhance the ability to improve the understanding of what drugs a patient is taking and what the possible interactions could be. This can apply to both the patients and the providers. Other assumptions of positive benefits relate to healthcare providers utilizing any clinical software that the extracted NDC number can be inputted into.

The negative benefits of the replacing the current NDC carrier with the QR code modification are built upon assuming that the patients, providers, and non-providers do not adopt this. The foundations of assumptions for both positive and negative benefits come from human interaction and behavior; therefore the negative benefits that are assumed relate to incorrect predictions of human behavior and smartphone user trends.

d. Risks from Positive Benefits

There are very minimal risks from the positive benefits. However, security is always a consideration in any form of risks. The positive benefits that were previously described involve increasing access, increasing information, and increased availability. It is possible that these increases will contribute to patients becoming lackadaisical with protecting data. There is a risk that if the full efficacy of the modified NDC carrier is achieved, and more healthcare data is placed on the carrier, users will begin to adopt the idea of easy access to healthcare information, which may have a negative reaction for other possible uses of QR codes. The benefits, once they are understood and fully adopted, may contribute

to users becoming too dependent on the technological abilities to easily access healthcare information. If other uses that require more data protection such as electronic health records (EHRs) are implemented, then users may be less likely to protect important healthcare information.

e. Risks from Negative Benefits

Risks from negative benefits can be associated with any loss of time and money that was invested into the implementation of the NDC carrier modification. If the negative benefits include that the patients, providers, and non-providers do not fully accept a QR code replacing the current NDC carrier's one-dimensional barcode, then there will be a risk of lost investment. The users are vital to the purpose to the goal of increasing the efficacy of the NDC carrier, and without the user's full support there is a risk of failure.

The loss of time can relate to the amount time involved in research, development, training, and implementation. All of these time losses can be associated with loss of money. For example, training level one providers, such as doctors and pharmacist, can be very costly when considering how much their work is valued per hour. There may be difficulties in convincing level one providers of the value that can be attained when going through the training.

3. How the Benefits Will Help Reduce Adverse Drug Events (ADEs)

The benefits of modifying the current one-dimensional NDC carrier with a two-dimensional QR code are associated with increasing the efficacy of the NDC carrier. This will allow more information to be stored and accessed. If the information stored provides knowledge about the drug that it pertains too, the person accessing that information will be more informed about the drug that he or she is taking. This benefit will help reduce ADEs by increasing patient, provider, and non-provider involvement in knowing what drugs a patient is taking, the information about the drug (dosage, instructions, warnings), and whether or not that drug is likely to interact with another drug that a patient is taking.

Involvement is a method to reduce ADEs. Each person's involvement may differ in regards to contributing factors, but all contributing factors play a role in reducing ADEs. By calling for "clinicians to enlist patients as partners," clinicians can make better treatment decisions through engaging and educating the patients and their families (Weingart et al., 2004).

a. *Patient Involvement*

Patient involvement is the front line for reducing ADEs. If a QR code that contains the NDC number and drug information on it is easily accessible, and if accessing the NDC number will benefit the usefulness of other drug management and interaction prevention applications, then the patient's role becomes the first contributing factor to reducing ADEs. A patient's role in reducing ADEs involves first accessing the information about the drug. Although drug names are typically on the bottles already, the only knowledge gained is when a patient visually reads the labels and drug information sheets.

The authors believe the ability to use mobile devices for the purpose of interacting with drug information can increase patient involvement. If a patient is able to scan a QR code and either extract information immediately or connect a NDC number to another database that either stores it or display any drug interaction, then the goal of patient involvement is successful. Patient involvement and increased knowledge contributes to preventative methods such as drug interaction prevention. If a patient is aware that a drug interacts, he or she can bring it to the provider's attention and receive consultation on whether or not the drug should be used.

A patient's knowledge of the drugs that he or she is taken is beneficial when switching pharmacies or physicians. There are still practices today where a patient is asked at the office or hospital visit to write down the names of any drugs he or she is taking including over-the-counter (OTC) and vitamins. Patients do not always remember the drugs that they are taking and/or do not know the drugs dosage. If the correct information is not documented, a

provider may prescribe a drug that normally would not be prescribed if a patient had listed certain drugs that cause interactions. Patient involvement by accurately collecting his or her own personal list of drugs is vital to ensuring that providers are able to document the drug information correctly. When a patient has the technological ability to quickly retrieve the correct drug information, and when that information can immediately be placed into a database that a patient can show a provider, there will be correct documentation that will help prevent ADEs.

Correct documentation is one of the factors that can help in the prevention of ADEs. Since our current national healthcare system does not contain electronic health records (EHRs) that can be accessed by any provider anywhere, there is a responsibility that still falls on the patients. This responsibility is for a patient to have full knowledge of and full access to his or her own personal drug information. However, this is on the first step in the ADE prevention process. Once this step of patient involvement, where the benefit from the use of QR code in the pharmaceutical industry, is fully understood and engaged upon, another sequential step must be taken. This next step consists of provider involvement.

b. Provider Involvement

Provider involvement refers to any level of provider who is involved in a patient's care where pharmaceuticals are prescribed, distributed, or managed. Provider levels of those involved can vary and include physicians, pharmacist, nurse practitioners, physician assistants, and nurses (RN and LPN/LVN). Provider involvement is vital to reducing ADEs. This is because decision making on which drugs are prescribed to a patient is made at this level. If the patient is able to present the providers with an accurate list of medication, the providers can accurately update the patient's drug list before prescribing a new drug. If a QR code is used, the providers can scan the code with a QR code reading device, whether it be a scanner or a smartphone with QR code scanning

capabilities. This method of scan the QR code and accessing the information directly is a way to help avoid human error that exists in manually inputting data.

In regards to provider involvement, the benefit of the QR code with respect to reducing ADEs is that QR codes hold information that may not be known or may easily be forgotten. The most important aspect of this technology is that it allows for information to be extracted. This extraction method is what providers can use, if they access the QR code directly, to populate other databases that manage drugs or provide alerts when a drug interaction exists. Because a QR code modification to the NDC carrier allows for a greater amount of information to be stored and retrieved, both patients and providers can work together to extract and manage information that is a factor in reducing ADEs. This factor pertains to an accurate depiction of all of the current drugs that a patient is taking. It is even important for the providers to know how many drugs a patient is taking because the more drugs a patient is taking, the higher the chance that he or she will fall victim to ADEs (FDA, 2009).

c. Non-provider Involvement

Knowing the drugs a patient is on and being aware of the interaction probabilities is also an important job for non-providers who are involved. For this research, non-providers are depicted as anyone who is not a provider and has an interest in a patient's healthcare to include prescription and non-prescription drugs. Non-providers can include family members, friends, or non-clinical caretakers. For these non-providers, the benefit of a QR code replacing the one-dimensional barcode as the NDC carrier is the ability for someone other than a patient or provider to be able to extract the same information.

Since a mobile device such as a smartphone or tablet is so readily available to non-providers just like it is for patients and providers, the QR code is beneficial for allowing non-providers to access drug information. Non-providers can scan the QR codes from a prescription and even non-prescription drug that a

patient is either taking or has in his or her possession. This can be very convenient and beneficial to drug management if a non-provider is able to collect the drug information without even getting the patient involved. This would refer to special cases where a patient is incapable of managing or gaining knowledge about his or her personal drug list.

Non-providers can also access free applications that allow them to create a drug list for the patient that they are helping to manage. These are the same applications that are made available to the patients and the providers. However, not all applications that are available to providers are available to patients and non-providers. Because of the popularity of the technological means to access information easily and quickly, there are adequate non-provider applications (mentioned previously) for managing prescription and non-prescription drugs. Some of the applications have the ability to extract data from the QR code once it is scanned and populate databases.

The benefit of the QR code for reducing ADEs in regards to non-provider involvement is to also ensure that the providers have accurate information for the purpose of making the best decision possible for a patient and preventing ADEs. Non-provider involvement is just as important as patient involvement, because the overall goal is to pass on correct information to whomever is prescribing drugs. Sometimes a non-provider may be the only means to which a provider receives information about the drugs that a patient is taking. The benefit of the QR code in this case is to help non-providers avoid human error and become more involved in accurately retrieving and forwarding drug information to providers or questioning when a drug interaction database provides an alert. An application that alerts if a drug interaction will take place can be beneficial by allowing a non-provider to be more confident in questioning drugs that are prescribed to a patient. This same concept can apply to the patient as well.

d. *Assumptions of QR Code Benefits Helping to Reduce ADEs*

It is assumed the benefit of the QR code will have a great enough contribution to reducing ADEs. Since the QR code by itself is not capable of reducing ADEs alone, it must be assumed that the patient, provider, and non-provider will fully become actively involved in their roles with the process. This should encompass every aspect of involvement, which includes an understanding of the importance of involvement, having access to the hardware (mobile devices), utilizing appropriate software applications, and learning time involvement.

Although the benefit of replacing the one-dimensional NDC carrier with a two-dimensional QR code centers on human involvement for reducing ADEs, it is still assumed that a NDC carrier modification will have any affect at all on reducing ADEs. The questions to consider that will be recommended for future research are the following: Can ADEs be reduced through patient involvement without any technological modifications? Are there other technological modifications that will have a greater impact on ADE reduction than QR codes will?

e. *Risks Involved in the ADE Reduction Process*

When technology is implemented and then relied on, there are risks involved with users becoming too dependent on the technology for information. Reliance on technology is not always beneficial when human decision making becomes less of a priority in the process. QR codes can be a beneficial factor in the process of reducing ADEs if they are understood to be a supporting role in human decision making. The risk of becoming so dependent on QR codes for information could result in a patient, provider, and non-provider assuming that the information retrieved is always correct.

It is possible that pharmaceutical manufacturers could place the wrong NDC number on the QR code. Although the chances of this happening are

no greater than the chances of it happening with the current process of creating the NDC one-dimensional barcode, there could still be a possibility. If the NDC number is incorrect, or any other pertinent information about the drug is incorrect, ADE reduction may be at risk. The reason it may be at risk is because of incorrect information being retrieved and evaluated by a provider before a new drug is prescribed.

Another risk that relates to technology dependence and reliance is the process of using drug interaction software for a patient's drug list. If the drug interaction software application does not recognize certain drugs that are known to interact or does not provide an alert to the user, there is a risk for an interaction. The risk comes from neglecting the experience and education that plays a role in human decision making. Technology may not be able to catch its own mistakes or report that certain drugs interact if it is not updated or if there is a possibility that a line of code written for the software application is incorrect. If technology involved in QR code usage in the pharmaceutical industry causes drug information to be incorrect, there could be a reverse effect on reducing ADEs, resulting in an increase in drug interactions.

f. Recommended Solutions to Reduce Risks Involved in the ADE Reduction Process

Since risks involved in the ADE reduction process are associated with becoming too dependent on the technology involved in QR code usage, solutions to consider are placing more emphasis on human decision making and less reliance on technology to always provide correct information. Human decision making still needs to be a priority when it comes to reducing ADEs. Making sure that a patient's drug list matches up what drugs are really being taken by the patient, a provider should verify each drug name with the patient. A provider should go over each drug name and describe what the drug is intended for as well as what family of drugs it is associated with. This way, if a patient does not recognize this drug, the provider could look up the NDC number to verify that it is correct on the QR code. Also, a provider can use his or her

education and experience to make the final decision on how much emphasis should be placed on trusting whether or not the information that was retrieved from a QR code is correct. Verification should always be practiced even if technology is used to provide information.

The suggestion to rely less on technology does not mean that there is not a strong case to use QR codes to reduce ADEs. This only means that risk reduction involves understanding that technology is not always 100 percent accurate. The objective of increasing the efficacy of the NDC carrier is to aid in increasing access to and knowledge of drug information. The utilization of software applications that can be associated with QR code information retrieval, information storage, and drug interaction alerts are support tools that also have positive roles in reducing ADEs.

4. Information that the Modified National Drug Code (NDC) Carrier Should Contain in Order to Contribute to the Benefits of Reducing ADEs

a. Suggested Information to be Placed in the NDC Carrier (QR Code)

The modified NDC carrier should at least contain the same information that is currently stored on the current NDC one-dimensional carrier, which is the 11 digit NDC number. Without this, the NDC would not exist and a barcode modification would not be necessary. The NDC number on the NDC carrier is what identifies each drug. This is what the patients, providers, and non-providers will use to correctly identify a drug that a patient is taking. This is the primary information that an NDC carrier should.

Next, in order to increase the efficacy of the NDC carrier there should be information that enhances a person's knowledge of the drug. This information should be beneficial to the objective of decreasing ADEs. Currently the information that is supposed to increase one's knowledge about a drug is located on the information packets that are distributed with the drugs that patient gets from a pharmacy. Since there is an abundance of information that is on the

packets, the important sections could be overlooked or ignored. The recommended use of the modified QR code is to place only the most beneficial information that would add to a patient's knowledge about a drug and help prevent ADEs. The information could include dosage information, directions, expiration date, initial production, warnings and risks, Web links and phone numbers to more information, and a list of known drugs that it interacts with.

It is also possible to place the entire information packet sheets on the QR code since it has the ability to hold a large amount of information. If the entire pack of information is placed on the QR code, the FDA could consider reorganizing the information in a way that is more conducive to the average reader and takes into consider a lower education level. The reorganization of the information could include the most important and easily understood information at the top. The format should be more enticing to the reader and any links to websites could use a blue font color as standardization.

The link that can be placed on the NDC carrier can take a user to the NDC directory. The NDC Directory contains a list of all drugs that are distributed in the U.S. According to the FDA (2012), registered drug establishments are required to identify and report their drugs to the FDA using the NDC. A user can search the directory by the following methods:

- Proprietary name search
- NDC number search
- Active ingredient search
- Application number or regulatory citation search
- Company search
- Proprietary name and company search

Since the NDC carrier will contain the NDC number, a link to the NDC number search field could be useful for the user, especially if the NDC number can automatically be inputted into the search field. This method of linking a user to the NDC director can be applied with or without the drug information packet sheets. However, using a Web link will require Wi-Fi or a mobile data

service. The purpose of the suggestion to place the information directly on the QR code with the link allows information to still be extracted whether or not a user has access to Wi-Fi or a mobile data service. This will decrease any risks associated with dependence on Web service.

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IV. EMERGENCY MEDICAL INFORMATION, EHRS, AND QR CODES

Emergency medical information can be defined as a list of essential health information that can help emergency medical personnel have a better understanding of a patient's medical condition. Emergency medical information should include personal identifiable information such as the patient's name, address, age, and phone number. It should also include the patient's emergency contact information such as next of kin, spouse, significant other, etc. In addition, the patient's blood type, medical information, such as allergies, current medications, surgical history, physician information, and insurance information should be included. The main benefit emergency medical information is that it provides critical information in a simple way. The information provided can greatly aid emergency medical personnel because it provides vital medical information up front.

This information is needed in situations where a patient is unconscious and/or is unable to communicate to emergency medical personnel. Emergencies such as this can happen at any time, and having emergency medical information readily available to first responders can mean the difference between life and death. For example, if an EMT responds to a scene with a non-responsive patient, having the patient's emergency medical information accessible would allow that EMT to make wiser choices as to the type of care to provide, and as to the types of medication to administer.

There are many current emergency medical information access technologies such as medical ID data cards, and medical ID bracelet/necklaces. In addition to these, the use of QR codes may result in the improved accessibility to emergency medical information. Medical first responders currently have limited ways of accessing the victim's emergency medical information; however QR codes may be an appropriate technology in this context. However, there are many challenges, including legal and security issues, that might prohibit their

adoption. In this chapter, we explore the potential uses for QR codes in emergency situation and survey the challenges associated with their adoptions.

A. CURRENT EMERGENCY MEDICAL INFORMATION ACCESS TECHNOLOGIES

Currently, there are limited ways for an individual to have a portable means of maintaining and displaying his or her emergency medical information. Current methods can range from a medical ID bracelet, a medical tag around one's neck, or a medical wallet card, also known as a medical ID data card

1. Medical ID Data Cards

Medical ID data cards contain emergency medical information, and may be carried in an individual's wallet or purse. The information on these forms can be hand-written or printed. These cards can be prepared locally by the individual, his or her clinician, can be purchased, or can even be created online at no cost (see Figure 24).


 EMERGENCY MEDICAL IDENTIFICATION Courtesy of MedIDs.com® John F Doe DOB: 01/01/1991 123 Anywhere Street Franklin, NY 02678 John.Doe@###.com 234-762-9988 - Blood Type:A+ Insurance: Insurance #:000-00-0000 Emergency Contacts: Sally Doe - Spouse - 234-888-9928 - Bobby Doe - Son - 456-987-1284 - Physicians: Frank Clark - 234-894-7722 Jessica Sinclair - 234-665-1122 Franklin General	Conditions/History: Diabetes Pacemaker Coronary Artery Disease High Blood Pressure Medications: Daliresp 5MG 1xDay - omeprazole 10MG 2xDay - Allergies / Other: Penicillin Bee Stings Organ Donor Card Printed: 4/24/2013 Courtesy of MedIDs.com®
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Figure 24. Sample medical ID data card (From MedIDs, 2013)

There are numerous benefits of a medical ID data card. They are easy to create, and easy to transport. The card can be easily carried in a wallet or purse. The card provides for a simple way for patients to document their list of medications when visiting their healthcare provider. In addition, emergency medical personnel will have access to the patient's family and physician

information in order to contact them in an emergency. While basic medical information is provided by a medical ID data card, this solution does not provide for the ability for a first responder or hospital emergency personnel to gain access to an individual's EHR. To have this ability, an individual would have to use a system that provides for the means for the first responders to gain access to the EHR data. This can be done via accessing a website with a unique username/password/pin associated with the patient, or dialing a toll-free number with the same username/password/pin. The assumption is that the patient would have previously made the decision to have this information available (pre-printed on the card) to a first responder in the event of an emergency. This would enable the first responder to gain additional and possibly more up-to-date medical information about the patient.

A limitation of a medical ID data card is that there can be too much medical information to be placed on the card. Doing so may make the card difficult to read or comprehend. In addition, medical information may change quickly, requiring constant updates, once printed, the data on the card is static, meaning that updated information would not be reflected on that card. The medical ID data card may not be easy to update and situations such as this. This can have severe repercussions if the emergency medical personnel are relying on this information to be accurate and up-to-date. In order to update the card, it might require a trip to the doctor, which may be a hassle.

Further complicating the matter, the responsibility of keeping the card up-to-date often falls on the patient. However, patients may forget what is and is not to up-to-date. An out-of-date card may be worse than no card at all. To compensate for this, the person choosing to use a medical ID data card should use a system that allows for the online update and printing of new cards with ease.

The durability of the card is also a question. If the card is made out of paper it can be easily damaged by rips, tears, smudges, etc. A damaged card can result in the information on the card being difficult to read. As in failing to

update the medical ID data card, a damaged card can also result in emergency medical personnel receiving incorrect patient information. To compensate for this frailty, the medical ID data card should be either laminated or made out of plastic.

Another limitation of the medical ID data card is advertising to the first responder that the patient has one in his or her possession. A first responder may not know, or may not have the time to look through an individual's wallet or purse in hopes that he or she has a medical ID data card. To compensate for this the individual should have a bracelet or necklace to notify the first responder of the existence of the card.

Perhaps the greatest limitation of medical ID data cards is the lack of privacy. The information on the card is readily available and easily viewed by anyone with access to the card. Because it is printed text, it is easy to apply encryption to the data. If an individual is concerned about his or her medical history and does not want this information to be available to unauthorized personnel, a medical ID data card may not be the right solution. If the card is lost or stolen still be no way to control who has access to that information.

2. Medical ID Bracelet/Necklace

Perhaps the most well-known of emergency medical identification access technology is the medical ID bracelet, or necklace. Emergency medical personnel often look around the patient's wrist for any identifying medical information. This form of medical ID is commonly worn by individuals with a medical condition, such as diabetes and/or a drug allergy, such as penicillin. These IDs typically have a medical alert emergency symbol (see Figure 25) displayed on them. This medical symbol was created by the American Medical Association (AMA), and it is worn to notify emergency personnel to "look for medical information that can protect life" (Universal Medical Identification Symbol, 1964).



Figure 25. Universal medical identification symbol (From Universal Medical Identification Symbol, 1964)

A medical ID bracelet/necklace can contain many of the same personal identifiable information as carried on a medical ID data card, such as the patient's name, address, etc. It can also carry emergency contact information such as next of kin, spouse, significant other, etc. These IDs can also have the patient's blood type, and physician information. Quite commonly however, they only have the patient's medical information, such as allergies, medical condition, and current medications. The information on these IDs are typically printed and come in a variety of styles and designs.

The benefit of a medical ID bracelet/necklace is that the universal medical identification symbol (created by the AMA) has been around for almost 50 years, is now common, and can be easily identified by emergency personnel. Another benefit of a medical ID bracelet/necklace is the ease of transport. The ID can be easily carried around the neck or wrist. Like the medical ID data card, it provides for a simple way for patients to provide critical medical information to first responders. As with the medical ID data card, the medical ID bracelet/necklace also does not provide for the ability for a first responder, and or hospital emergency personnel to gain access to that individual's EHR. A system that provides for the means for the first responders to gain access to the EHR data

would also be required in this case this can also be done via accessing a website with a username and password, or dialing a toll-free number with the same username and password.

The limitations of a medical ID bracelet/necklace are numerous. They are not easily created by the individual and so must be purchased from a company that provides custom engraving. The cost to procure this type of ID is substantially more than that of a medical ID data card. Due to these limitations, a medical ID bracelet/necklace may not be suitable for all individuals.

The information on a medical ID bracelet/necklace is not easily updated. Because it is so static in nature, the information placed on the bracelet/necklace should be things that are relatively static in nature (e.g., the person's name, medical condition, or allergies). The purpose of these IDs are to notify first responders that the individual has a medical condition, and not necessarily all the other identifiable information discussed above.

Perhaps the greatest limitation of a medical ID bracelet/necklace is the lack of space available to display all the desired information. These IDs are typically pendant or dog tag sized. Due to the nature of the design, a bracelet holds significantly less information than that of a necklace (see Figure 26 and Figure 27). The information placed on these types of IDs has to be carefully thought out by the individual; one cannot place all PII, emergency contact information, physician and insurance information, as well as medical information on the ID. Only critical or life-saving information should be placed on IDs of this type.



Figure 26. Medical ID bracelet (From Oneida Medical Jewelry, 2013)



Figure 27. Medical ID necklace (From Oneida Medical Jewelry, 2013)

B. IMPROVED ACCESSIBILITY TO EMERGENCY MEDICAL INFORMATION, AND EHRs VIA QR CODES

QR codes can be produced with great ease, and can be produced by anyone. There are many advantages that a QR code can provide in providing emergency medical information. This section will discuss three ways to implement the use of QR codes in this arena, using terms called Direct-encoded, Indirect-encoded, and Hybrid QR codes. The benefits and limitations of these codes will also be addressed.

1. Overall Benefits of Using a QR Code for Emergency Medical Information

Due to their robust error correction, QR codes are resilient to damage. QR codes can be read easily, are easy to transport, and are highly customizable (Bennett 2012). In addition, QR codes can provide for an immediate, real-time access to medical information (Langford & McCoy, 2013). They provide an efficient way for clinicians with no access to a patient's EHR to gain some level of understanding with regards to the patient's current medical condition (Langford & McCoy, 2013). This is especially useful for clinician that is meeting patient for the first time.

2. Overall Limitations of Using a QR Code for Emergency Medical Information

There are very few limitations to using QR codes to store emergency medical information. One of those limitations is that a device capable of reading and decoding QR codes is required. The initial time it takes to create and print the QR code may also be considered a limitation, albeit a small one. It also takes a small level of training to learn how to scan a QR code. Depending on the type of QR code used, Web connectivity may be required to obtain all relevant emergency medical information.

3. Direct-Encoded QR Codes for Emergency Medical Identification

Direct-encoded QR codes are codes that contain information that cannot be updated once generated. These types of codes can be ideally used to store emergency medical information. The use of these codes preclude an individual from having to constantly update his or her QR code whenever the medical information changes. The users of this code should ensure that the information placed on the code is fairly static in nature, meaning that the information will not change from time to time.

See Figure 28 for an example of what a direct-encoded QR code used to store emergency medical information looks like. As shown, the card has the patient's name, the universal medical identification symbol, as well as a QR code. There is also information notifying a first responder to scan the QR code to access additional emergency medical information. A direct-encoded QR code of this nature is very simple in its design.

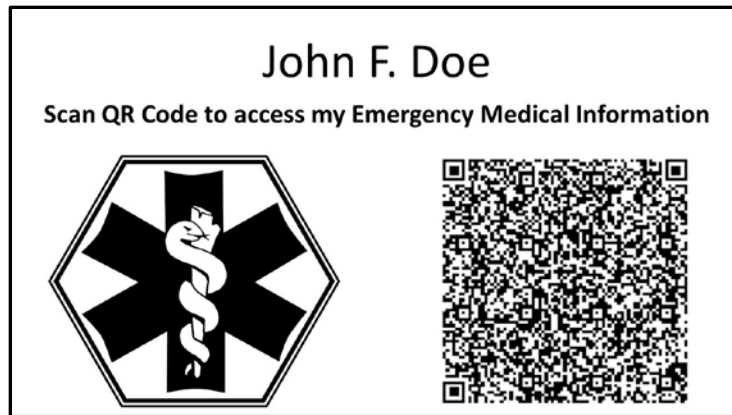


Figure 28. Sample direct-encoded QR code

Figure 29 shows the medical information that is stored within the direct-encoded QR code. For example our John Doe has chosen to store his name, gender, date of birth, height, weight, and blood type. This basic identifiable information is fairly static in nature and most likely will not change over time, thus not requiring John Doe to update his QR code on a frequent basis. Additional information stored on this card includes emergency contact information for John Doe. Any medications currently being taken, as well as allergies and current medical conditions also stored on the direct-encoded QR code. The date the QR code was last updated is also stored. This data is stored as to provide information to the first responder as to how dated this information may be. For example if the last time this QR code was updated was a few years in the past, it may cast some doubt as to the accuracy of the information, especially the medical condition and current medications.

<p> NAME: John F. Doe SEX: Male DOB: 01Jan1992 HT: 5ft. 11in. WT: 185 lbs. BLOOD TYPE: A+ PHONE: (234) 762-9988 </p> <p> EMERGENCY CONTACTS: Sally Doe (Spouse) – (234) 888-9928 Bobby Doe (Son) – (456) 987-1284 </p> <p> MEDICATIONS: Daliresp (5 mg – 1xDay), Omeprazole (10 mg – 2xDay) </p> <p> ALLERGIES: Penicillin (life threatening), Bee Stings (severe) </p> <p> CONDITIONS: Diabetes, Pace Maker, Coronary Heart Disease, High Blood Pressure </p> <p> Date updated: 04Jan2013 </p>
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Figure 29. Sample medical information stored in a direct-encoded QR code

4. Indirect-Encoded QR Codes for Emergency Medical Identification

Indirect-encoded QR codes are codes that contain limited information, but contain a link to a website with additional information. These types of codes should also have the basic medical information stored in them, and should be used by an individual that has constantly changing medical information. Users of this type of code do not necessarily need to worry about the accuracy and timeliness of the information placed on the code due to the majority of the information being available online.

An example of what an indirect-encoded QR code used to store emergency medical information looks like is shown in Figure 30. As the figure shows, the look of the card is basically identical to the direct-encoded QR code. It also has the patient's name, the universal medical identification symbol, as well as a QR code. As with the direct-encoded QR code, there is also information notifying a first responder to scan the QR code to access additional emergency medical information. As with a direct-encoded QR code, an indirect-encoded QR code is also very simple in its design.

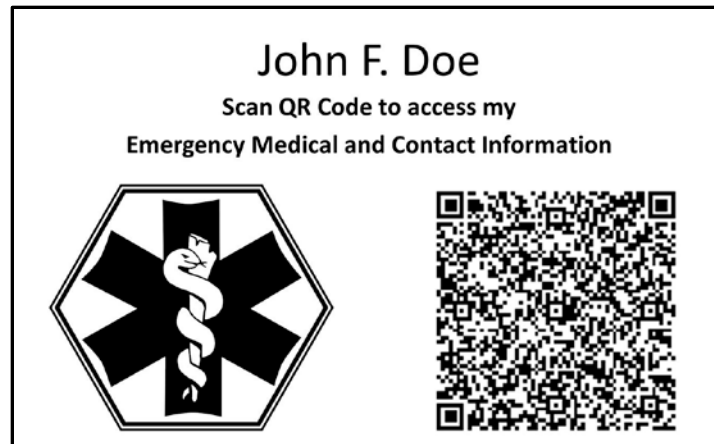


Figure 30. Sample indirect-encoded QR code

Figure 31 shows the medical information that is stored within the indirect-encoded QR code. In this example, our John Doe has chosen to store his name, gender, date of birth, and blood type on the QR code. He is also chosen to store his allergies on the code, as most allergies do not change over time. In this example provided, our John Doe would most likely never have to update his QR code in the future. In contrast to the direct-encoded QR code, all emergency contacts, medications, and current medical information are not readily available within initial scan of the code.

In contrast to the direct-encoded QR code, there is a notification stating that additional medical information can be obtained by accessing a website. A user ID and password is also provided in order to obtain access to the website. There are certain privacy and security concerns with having the user ID and password so readily available. These concerns will be addressed further on. As the figure shows, not much information is stored on these types of codes. There are advantages and limitations of choosing a code of this type, to be discussed later.

NAME:	John F. Doe	SEX:	Male	DOB:	01Jan1992
BLOOD TYPE:	A+				
ALLERGIES:	Penicillin (life threatening), Bee Stings (severe)				
Go to:					
http://www.mytestmedicalrecord.com/doeid1					
for additional medical and contact information					
User ID: 261723			Password: 242784291		

Figure 31. Sample medical information shown in an indirect-encoded QR code

5. Hybrid QR Codes for Emergency Medical Identification

Hybrid QR codes are a combination of direct-encoded and indirect-encoded QR codes. They contain a significant amount of information, and also contain a link to a website that has additional information. As with the direct-encoded QR code, as much medical information as possible should be placed on the hybrid QR code. This type of code tries to take advantages of the benefits that both direct-encoded and indirect-encoded codes provide. They can be used by an individual that has constantly changing medical information, as well as an individual with fairly unchanging/stable medical information. These types of codes are also ideally used an individual that is not concerned about the privacy of his or her medical information, due to the amount of information stored.

A typical user of a hybrid QR code, can choose to place as much information as possible (as in a direct-encoded card), to aid a first responder in obtaining the critical medical information quickly. Users of this type of code are typically worried about the accuracy and timeliness of the information placed on the code due, even though additional medical information is available online. This is mainly because of the vast amount of information that is stored on the code

An example of what a hybrid QR code used to store emergency medical information looks like is shown in Figure 32. The look of the card is basically identical to that of the direct-encoded and indirect-encoded QR code. It also has the patient's name, the universal medical identification symbol, as well as a QR code. As with the direct-encoded and indirect-encoded QR code, there is also information notifying a first responder to scan the QR code to access additional emergency medical information. As with a direct-encoded and indirect-encoded QR code, a hybrid QR code is also very simple in its design.

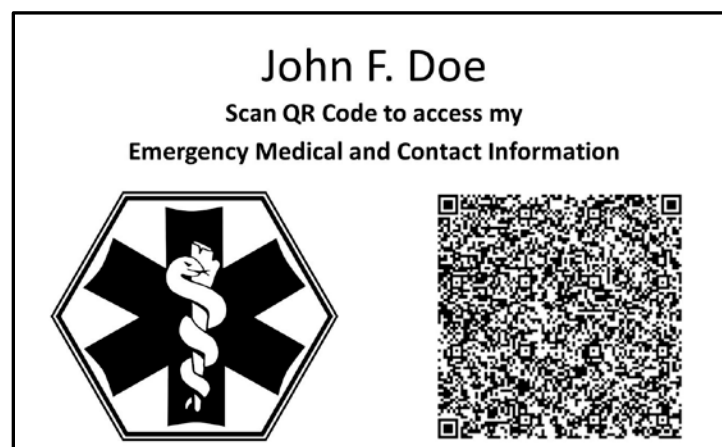


Figure 32. Sample hybrid QR code

The medical information that can be stored within the hybrid QR code can be seen in Figure 33. In this example our John Doe has chosen to store the exact same information that was stored in the direct-encoded QR code. This hybrid QR code example stores John Doe's name, gender, date of birth, height, weight, and blood type. The basic identifiable information is fairly static in nature and most likely will not change over time. Additional information stored on this card includes emergency contact information for John Doe, any medications currently being taken, as well as allergies and current medical conditions. As with an indirect-encoded QR code, there is also a notification stating that additional medical information can be obtained by accessing a website. A user ID and password is also provided in order to obtain access to the website. In contrast to

the indirect-encoded QR code, the date the QR code was last updated is also stored. As with the indirect-encoded QR code, this data is stored as to provide information to the first responder as to how dated this information may be. For example, if the last time this QR code was updated was a few years in the past, it may signal the first responder that he or she may want to login to the individuals EHR website to obtain more up-to-date medical information.

John F. Doe's Hybrid QR Data

NAME: John F. Doe **SEX:** Male
DOB: 01Jan1992 **HT:** 5ft. 11in. **WT:** 185 lbs.
BLOOD TYPE: A+ **PHONE:** (234) 762-9988

EMERGENCY CONTACTS:
Sally Doe (Spouse) – (234) 888-9928
Bobby Doe (Son) – (456) 987-1284

MEDICATIONS: Daliresp (5 mg – 1xDay), Omeprazole (10 mg – 2xDay)

ALLERGIES: Penicillin (life threatening), Bee Stings (severe)

CONDITIONS: Diabetes, Pace Maker. Coronary Heart Disease, High Blood Pressure

Go to: <http://www.mytestmedicalrecord.com/doesjd1> for additional medical
and contact information
User ID: 261723 Password: 242784291

Date updated: 04Jan2013

Figure 33. Sample medical information shown in a hybrid QR code

C. BENEFITS AND LIMITATIONS OF THE USE OF QR CODES TO ACCESS

There are multiple ways for first responders to access an EHR. This section will discuss the benefits and limitations of using direct-encoded, indirect-encoded, and hybrid QR codes to access EHRs in an emergency/first responder situation.

1. Direct-Encoded QR Codes

Direct-encoded QR codes can be used to store and emergency medical information that is fairly static in nature. One of the benefits of these types of codes is that all the relevant emergency medical information is readily available to the viewer. With the exception of initially scanning the QR code, gaining access to this information does not require any additional work by the EMT. That can be considered a benefit because depending on the criticality of the patient, the EMT may not have time to go online to obtain additional medical information. Another benefit of direct-encoded QR codes is that they do require no Web connectivity. All required information is locally stored. This allows for the EMT to obtain the information that he or she needs, without being overwhelmed with additional Web provided data.

A major limitation of direct-encoded QR codes is that an individual is limited by the amount of space/storage that a QR code provides. If a patient has an extensive medical history, all required important information may not be stored on the QR code. Another limitation of direct-encoded QR codes is that it does not give access to an online EHR. In addition once generated, the information on a direct-encoded QR code cannot be updated even if there are changes to that information. For an individual to update a direct-encoded QR code, that QR code would have to be regenerated, and reprinted. If the direct-encoded QR code was placed on a bracelet or necklace it would make it quite tedious to update the information.

2. Indirect-Encoded QR Codes

Indirect-encoded QR codes are codes that contain limited information, but contain a link to a website with additional information. A benefit of the indirect-encoded QR code approach is that space and storage are not major concerns, because the majority of the medical information data is stored in an online database. Another benefit of this approach is that if the medical data needs to be updated, it can be easily done so via online without requiring the QR code to be

updated and reprinted. If the patient has an extensive medical history, it is all captured in the online EHR. Another significant benefit of indirect-encoded QR codes is that it gives full access to that online EHR. This type of QR code only has the critical/non- changing information about the patient, so once generated it will more than likely not need to be updated again. This provides for good solution for necklaces and bracelets.

There are a few limitations to indirect-encoded QR codes. Perhaps the greatest limitation is that it requires Web and that too Beatty for it to be useful. This may not be ideal and/or appropriate in an emergency medical situation due to the extra step required to obtain the medical information. Emergency contact information, insurance information, and physician information, etc... is not available unless via the online database. This can result in loss of timely access to patient information and/or the loss and timely providing of patient care.

3. Hybrid QR Codes

Hybrid QR codes are a combination of direct-encoded and indirect-encoded QR codes. They contain a significant amount of information, and also contain a link to a website that has additional information. A benefit of hybrid QR codes is that all significant medical information is readily available to the EMT. The EMT is not required to perform any additional tasks after the code is scanned. Another benefit of these codes is that no Web connectivity is required to obtain the information stored on the code. The space and storage limitation of a QR code is also not a concern, since the majority of the data can be stored in an online database. If that data is required by the EMT it can easily be accessed. In addition, if the information online needs to be updated it can be easily done so without having to create a new hybrid QR code. If an individual has an extensive medical history, a hybrid QR code would be ideal, because the history can be stored in an online EHR. A hybrid QR code gives first responders full access to the patient's EHR, and provides the best of both worlds (direct-encoded and indirect-encoded QR codes).

There are limitations to hybrid QR code however, perhaps the greatest limitation being the requirement for Web connectivity. If the patient has an extensive medical history, all relevant medical information, or important information may not be able to be stored on the QR code. If a first responder's device used to scan QR codes does not have Web connectivity, critical information may not be available when needed. Another limitation of hybrid QR codes are that if the individual chooses to place an extensive amount of information on the code, once generated that information cannot be updated without creating a new code. If this code is on a necklace or bracelet it can be quite tedious to update. A hybrid QR code may not be used and/or be appropriate in some emergency situations due to the extra step required to obtain information.

D. USES OF EMERGENCY MEDICAL INFORMATION, AND EHR ACCESS TECHNOLOGIES BY MEDICAL FIRST RESPONDERS

1. How We Visualize a First Responders EHR Access Capabilities Today

When a first responder responds to a medical situation, that individual may or may not have access to the current patient's medical condition, allergies, and current medications. That first responder has to rely on any information readily available, or medications that are stored in the patient's medicine cabinet. This will give the first responder a picture of the patient's current medical condition. First, responder does not know the patient's medical condition, allergies, and current medications. Currently, it is up to the first responders to make a "best guess" about the patient's medical condition allergies and medications. The authors believe that this could result in the administering of emergency medication that can cause adverse drug events, or adverse allergic reactions.

When called to a scene, the first responder can only utilize the information that is readily available to them. Some patient's may have a medical ID bracelet or necklace but it is most likely that the mass majority of patients will have no

medical condition identifying information. The authors feel that in situations as these the first responder will be in a position that weakens his or her ability to provide appropriate care without the risk of harming the patient. When the patient is transferred to a higher level of care (ambulance, hospital, etc.), the same uncertainty that the EMT faced will also be faced by the medical personnel at that high level of care.

Without immediate access to a patient's current medical condition, allergies, and medications, those that are providing care to the patient, are essentially "rolling the dice" with respect to the overall health of the patient. Without a standard for the access of this information, and for the access of EHRs, this problem will continue to perpetuate, and continue the results in the loss of lives. Current EMT personnel, and first responders, do not have sufficient, and or timely access to a patient's medical information, allergies, current medications, and EHR.

2. How QR Codes Can Help

The authors feel that with the use of QR codes, first responders will be able to greatly enhance the timeliness and quality of patient care provided to the individual in need. If the EMT or first responder has access to a device capable of scanning a QR code and storing emergency medical information she/he would be able to obtain that information with ease. The information provided on this code would do the EMT in making decisions with respect to the administering of medication to John Doe.

As depicted in Figure 34, the EMT would be alerted that John Doe has critical medical information that he would like to share, because of the universal medical identification symbol shown. The EMT can then use his or her smart phone to scan John Doe's QR code thus gaining access to John's emergency medical information. As stated earlier, this QR code can be in the form of the card, a bracelet, or necklace. The EMT would have, with a great deal of certainty John Doe's blood type, emergency contacts, medications, allergies, and his

current medical conditions. The EMT would also be able to tell when the last time that John Doe updated this information. Figure 34 depicts the process by the EMT would follow for a direct-encoded QR code containing medical information. Because it is direct-encoded code, the EMT would not require any Web connectivity for additional information. In the brief time it would take the EMT to scan the direct-encoded QR code, he or she would gain enough information to prevent the administering of medication that John Doe may be allergic to. This information would aid in the reduction of John Doe having an ADE.

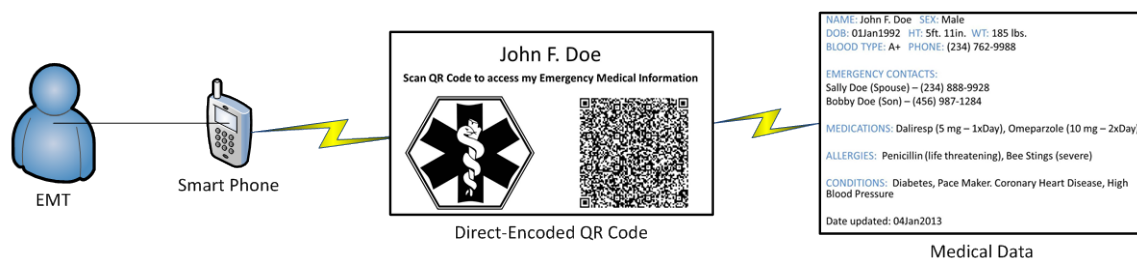


Figure 34. EMT process for accessing data from a direct-encoded QR code

Figure 35 depicts a similar scenario as in Figure 34; however John Doe now has an indirect-encoded QR code. The initial information now provided to the EMT is basic in nature, the QR code on the shows John's blood type and allergies. The EMT is also notified that if additional medical information is required c can access John's EHR via the website, username, and password provided. In this scenario Web connectivity would be required if the EMT needed John's additional medical information. Based on the criticality of John's injury, the EMT may or may not have time to access the EHR online. In a situation such as this, when John is transferred to a high level of care, the clinician in charge of John's care may then choose to access John's EHR for additional information.

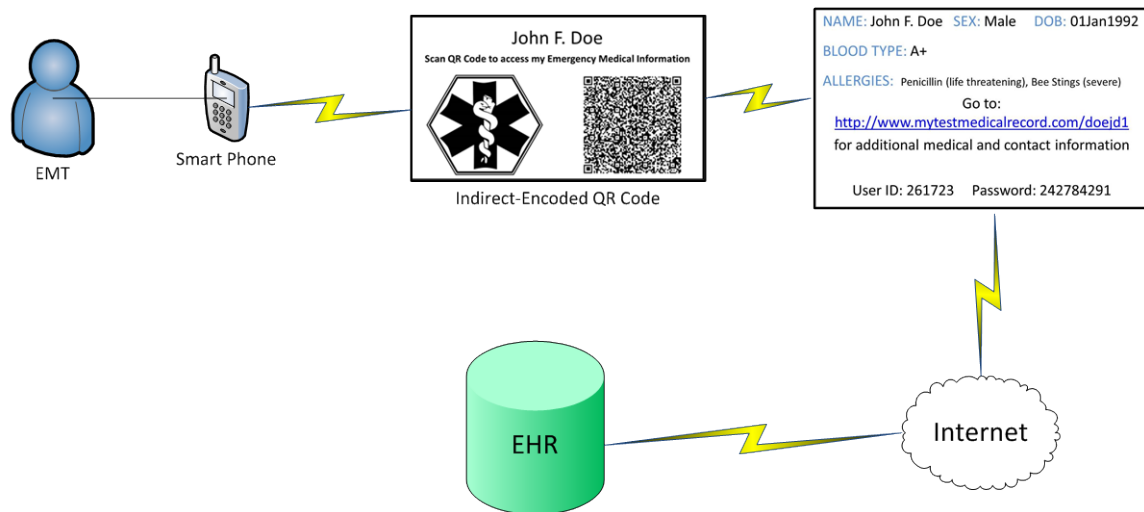


Figure 35. EMT process for accessing data from an indirect-encoded QR code

3. Assumptions of QR Code Usage for EHR Access

There are some assumptions that must be made when it comes to using QR codes to access an individual's emergency medical information, and EHR. These assumptions are not exhaustive in nature, but cover the majority of scenarios that can be possibly faced. These assumptions are realistic in nature due to the ubiquity of smart devices in our culture today. Assumptions made are that:

- First responders will have a device capable of reading QR codes.
- The individual and/or clinician will have access, and the ability to create the QR codes.
- The individual and/or clinician will have access and the ability to print out the QR codes.
- The individual and/or clinician will have a device capable of reading QR codes.
- For all situations requiring an EHR, that the individual will have a service that provides and maintains that online EHR.

E. SECURITY ISSUES RELATING TO QR CODE USAGE FOR EHR ACCESS

This section will discuss the security and privacy concerns of using QR codes access emergency medical information, and EHR data. The confidentiality, integrity, and availability of the patient's EHR data are also discussed.

1. Privacy

Perhaps the main issue relating to QR code usage for accessing emergency medical information, and EHR access is that of privacy. Individuals choosing to use QR codes should be well aware of the possible compromise in the privacy of their data. The individual must make the conscious decision to trust the QR technology, and must be willing to put his or her private information on the QR code. This decision is no different when a medical ID bracelet is worn, and there is often a trade-off between privacy and empowering caregivers. With that said QR codes are somewhat private in that they cannot be and then decoded by the naked eye, because they require a device that can read and decode them.

The access of EHR on the cloud, via the use of mobile device as a thin client provides numerous benefits. The EHR data can be accessed via a browser or an App without requiring much to be executed on the client. The complex EHR documentation application can be executed on powerful servers and not on the mobile device, providing for greater functionality, better performance, and additional security (Kim, Baratto, & Nieh, 2006). One of the best reasons to use a mobile device as a thin client is that the EHR data on the device does not need to be backed up or restored. No EHR data is actually stored on the mobile device. In addition the EHR data on the QR code once generated also does not need any additional restoration. All information is stored on the QR code. No maintenance would be required to be performed on the

smart device, and the smart device would not store any sensitive data that can be lost or stolen (Kim et al., 2006). This feature of using mobile devices and QR codes to access EHR data helps with privacy concerns.

2. HIPAA

The Health Insurance Portability and Accountability Act (HIPAA), is the Federal Law provides a conceptual guideline that must be strictly observed by all followed organizations (Public Law 104-19, 1996). The HIPAA specifically indicates that patients' privacy should be emphasized (Lee & Lee, 2008). The crucial part of the HIPAA comprises its privacy and security regulations, and it provides for guidelines to protect patients' privacy and health information security. HIPAA requires that all confidential sections of the EHR must be protected. This includes data as it is being transmitted, viewed, and retrieved. With regards to the use of QR codes to access the patient's EHR, the patient's online vendor of choice EHR provider would have to ensure that he or she is HIPAA compliant. If the patient chooses to store his or her emergency medical information, as well as a username and password on a QR code, then he or she has made the conscious decision to waive his or her HIPAA rights.

3. Confidentiality

The best way to maintain confidentiality of EHR data is through the use of encryption to transmission, storage and retrieval stages. Encryption can make personal health information (PHI) unreadable during storage and transmission, and is a suitable way to keep electronic PHI secure and to prevent disclosure without appropriate authorization (Lee & Lee, 2008). Access control to EHR data and to the EHR documentation medium can be maintained by authenticating authorized users via biometrics, a PIN, or username and password.

4. Integrity

The use of a digital signature via biometrics, username and password, and additional methods, can be used to provide integrity to EHR data. Under HIPAA

regulations, the safeguarding, and data integrity of EHR data is important. Medical omissions, tampering, and the unauthorized destruction of health information are prohibited (Public Law 104-19, 1996). In addition, to help maintain data integrity, records should only be updated and transmitted to the patient is EHR only after the transaction has been digitally signed by the provider performing the medical care, or the patient is updating his or her record. Data integrity needs to be guaranteed for ensuring a patient's safety (Lee & Lee, 2008).

The use of a digital signature provides the best integrity and non-repudiation, because the signer uses the private key to sign a message, and the verifier uses the corresponding public key to verify the signature. Because the private key is unique and known only to the signer, the nonrepudiation and authenticity of the signed EHR data is guaranteed (Lee & Lee, 2008).

5. Availability

A key concern of the use of QR codes to obtain medical information is the availability of that medical data when it is needed. Users (both patients and EMTs) would have to rely on the EHR vendor of choice to exercise appropriate security measures at the location of where the medical data is stored, and because of this, cloud security is an issue of utmost importance (Dhage & Meshram, 2012). With regards to cloud computing, there are two types of security; data security, and network security (Dhage & Meshram, 2012). Data security focuses on protecting the software and hardware associated with the cloud (such as the location of the EHR data centers), and network security protects the network over which the cloud is running from various attacks (such as denial of service, and spoofing) (Dhage & Meshram, 2012). These security issues, as well as end-to-end security, privacy, and business integrity and continuity are of greater complexity in a cloud-computing environment than in a single data center (Chakraborty, Ramireddy, Raghu, & Rao, 2010).

The loss of availability to EHR data is a potential risk of using cloud services, to include the loss of direct control of resources and increased liability (Chakraborty, Ramireddy, Raghu, & Rao, 2010). These risks come with sharing external resources, because there is a greater risk of security breaches and data leaks with cloud computing. The vendors of choice would need to ensure that they too had a strict network and data security guidelines, to ensure the availability of EHR data when needed by medical personnel.

F. SUMMARY

The current emergency medical information access technologies that are available to medical first responders do not do enough, will provide the information that the first responders need to reduce medication errors. The use of QR codes in a direct-encoded, indirect-encoded, and hybrid way will provide numerous benefits of this field. QR codes can allow for the easy access to EHR data, as well as emergency medical information. Victims, family members, emergency medical personnel, and clinicians can all benefit from the use of QR codes. The security issues relating to the use of QR codes to access emergency medical information and EHR data needs to be taken in consideration prior to and during implementation. Vendors of choice that maintain the EHR data must ensure that they remain compliant with current regulations.

V. MERGING THE RECOMMENDED NDC CARRIER WITH THE EHR TECHNOLOGICAL MODIFICATION

In order to decrease ADEs, human involvement is a necessary means to understanding what drugs a patient is on and whether or not there will be an interactions with current or forthcoming prescription drugs. How a QR code can improve the efficacy of the NDC as well as the access to emergency medical information and EHR has been discussed. The merging of these two ideas into an overarching methodology that will result in the reduction of ADE's and the improved access to emergency medical information will now be discussed. The technologies in this case should only be used as a tool to aid in human involvement and provide data that supports good decision making. Patients, providers, and non-providers involved in a patient's healthcare and drug management should seek all means necessary to ensure that the healthcare information, especially drug management information, is correct and up to date.

A. THE MODIFIED NDC CARRIER COUPLED WITH AN EHR RESULTS IN DECREASING ADE'S

QR codes are an emerging technology that can increase the efficacy of the NDC carrier as well as store vital health information that can easily be accessed by patients, providers, and non-providers involved in a patient's care. Since mobile computing via a smartphone, tablet, or any other mobile computing device is on the rise and there is no indication of a decline, it is inevitable that users will continue to seek methods or software applications that allow their mobile hardware devices to feed them the information that they need for decision making.

If human involvement in drug management is not improved, ADEs will continue to increase and kill over 100,000 people each year. Since previous research indicates that a relationship exist between drug information and health records, there is a need to link the two in order to affect the outcome of ADEs.

This is vitally important because decreasing ADEs depends on the following two independent variables: drug information accessibility and health records containing correct drug information.

The theory of decreasing ADEs that relates decreasing ADEs to human involvement in drug management and the theory of human involvement in drug management that relates human involvement to accessing drug information and storing correct drug information in a patient's health record will now be discussed. This is important because human involvement in drug management requires that a health record, whether it is electronic or paper based, be populated with the most up to date and correct patient drug information in order to prevent an ADE from occurring. For the purposes of our recommendations, human involvement is defined as a patient, provider, and non-provider with the ability to access and gain knowledge of a patient's drug record. The modified NDC carrier (QR code) is defined as a QR code that contains the NDC number and other pertinent drug information. In increasing human involvement in drug management and decreasing ADEs is the main focus.

Our goals are to first to demonstrate how the use of QR codes will increase human interaction with the information that is stored on them. Secondly, will demonstrate that by storing the NDC number on a QR code will result in the drug information being easily accessible from the drug bottle and the EHR. Finally will demonstrate that the technological modification of using QR codes to store EHR and drug information such as the NDC number will result in the reduction of ADEs. All three of our goals address the theory of increasing human involvement in drug management, which will result in decreased ADEs.

1. How the Use of QR Codes Will Increase Human Interaction with Them

Previous research supports that mobile technology use is on the rise and QR code usage for marketing has been proven successful. Using QR codes to market businesses and products is a technological improvement in the way

human interact with information. This is analogous to human involvement in drug management. Studies that reveal how QR codes have impacted the marketing world can be used to support whether or not QR codes will be useful in the healthcare industry.

However, research did not indicate how drug list would be updated or even populated in the beginning. The assumption is that a patient would be responsible for getting the correct information into the QR code or to the administrator of the QR code. This is an important aspect of decreasing ADEs, because health records must contain correct drug information for a provider to make a correct decision when it comes to prescribing.

Since a large number of people scan QR codes just to see the marketing information on them, it is inevitable that QR codes which contain information that is associated with one's personal wellbeing will be utilized even more. On-demand is a buzzword that associates the promptness that a user wants to access data. This is becoming a requirement for business to keep up with a growing trend of mobile device user who expect to access data immediately. Attempting to increase human involvement in drug management will require understanding the trends and meeting the desired expectations of users who are also patients in the healthcare field.

One important aspect about QR codes in business marketing is that they make a customer feel connected with the product. Because of the growing use of mobile devices for mobile banking, social websites, and e-mail, the hardware itself can be seen as a personal item. With the innovations in banking, users can now pay for products with just their mobile device. The mobile innovations of today can allow a user to be completely functional with only a mobile device such as his or her smartphone to take care of everyday needs. Since mobile devices have the ability to handle personal transactions and extract personal information, the hardware is seen as a personal device in which a user can feel a sense of personal attachment to. This provides strong support for the successful emergence of the QR code and its use potential in human involvement in drug

management. The goal to increase human involvement must start with making a user become aware of the need for information and to associate that need as being a personal one. Since businesses see the QR code success coming from personally being involved in a dynamic marketing world of information as opposed to static marketing on posters, billboards, and magazines, the healthcare industry can predict that QR codes will contribute to an increase in health information access and knowledge.

2. Storing the NDC on a QR Code Results in the Easier Access of Drug Information.

The National Drug Code, an 11 digit drug identifier (Berman, 2004), was created in 1969 by the Federal Drug Administration (FDA) so that drug manufacturers, distributors, hospitals, insurance companies, and the government could have an identification system that automatically processes drug data using a computer language (Rodgers, 2012). This automatize computer process would increase efficiency and data accuracy resulting in fewer human errors in drug distribution.

The NDC, created to reduce human error and track drugs, is a national identifier that has proven to be used successfully in the pharmaceutical industry. This national identifier that is placed on a linear barcode can be accessed by patients who have one-dimensional barcode scanners and software capable of defining the NDC number. However, this is not feasible and is an outdated form of technology. Since the QR code has proven to be a more efficient and reliable barcode and is compatible with hardware and software that is currently made available to the average mobile device user, replacing the current NDC carrier with a QR code will increase the efficacy of the carrier. If the replace QR code, which will hold the NDC number, is placed on a drug bottle, patients will be able to extract the NDC number using their mobile device. If specific information about the drug is placed on the QR code, then patients will have access to that information as well. Allowing a patient to access the NDC number from his or her

drug bottle opens doors to other possible uses for the drug identifier. This would also be available to providers and non-providers who are involved in a patient's drug management.

The QR code can also be used store data from a patient's health record in the form of an electronic health record. The data should include a patient's drug list and can contain a NDC number that identifies a drug. Software capable of defining the NDC number and associating the actual drug name with the identifying NDC can provide information about the drug and ensure that the correct drug that a patient is taking is properly identified by a provider.

3. Using QR Codes to Store EHR and Drug Information Result in the Reduction of ADEs.

By making drug information easily available on a drug bottle or in a patient's health record and by providing a way to input the correct information into a patient's health record will lead to a five percent decrease in ADEs. This is based previously mentioned statistics that approximately percent of mobile device users are scanning QR codes. If 14 million (approximately five percent) out of 302.6 million smartphone users around the world are scanning QR codes, it is safe to assume that at least five percent of Americans who use mobile devices are scanning QR codes. The five percent decrease will cover all individuals who are and could be victims of ADEs whether they have smartphone or not based on a five year forecast that 100 percent of Americans will own a smartphone or mobile device capable of scanning a QR code. The 100 percent includes any of the following types of human involved in a patient's drug management: patients, providers, and non-providers involved in a patient's drug/healthcare management.

Other support for QR code usage by way of smartphones can be validated by current trends in cellular phone plan availability. Any customer or potential customer who goes to a cellular phone carrier's website to search for any individual or family plans that are compatible with basic phones (phones that are

not smartphones) will find a very limited availability of plans. Some carriers make it very difficult to find any plans that are not associated with smartphones. It is assumed that cellular phone carriers are contributing to the rapid increase in smartphone users by slowly eliminating basic plan options

Human involvement, availability of drug information, and assumptions of smartphone users who will scan QR codes all lead to a theory that ADEs will be reduced through the implementation of QR codes in the healthcare industry. If a QR code is placed on a drug bottle with practical drug information, and if a QR code can contain an EHR with either the correct NDC number that contains a link to drug information or if the drug information is automatically populated in the EHR when the modified NDC carrier (QR code) is scanned then there will be a greater chance of preventing ADEs. This is based on previous research that human involvement, provider knowledge, and correct drug information will contribute to preventing ADEs. If technological modifications of the NDC carrier can support the previous research and predicted outcomes, then it will decrease ADEs by five percent.

B. THE REDUCTION OF ADE'S FOR PATIENTS WITH, AND WITHOUT AN EHR BY USING QR CODES.

The use of QR codes with NDC's, EHRs, and emergency medical information would result in the reduction of uncertainty faced by medical providers. It will be demonstrated that by using QR codes, a patient with or without an EHR will have a lesser chance of experiencing an ADE. A few scenarios from the perspective of a clinician at the doctor's office, an EMT, and a pharmacist all tasked to administer drugs to a patient will be looked at. For the purposes of the scenario, the assumption is that all recommendations discussed earlier were implemented by all actors in the scenario. The assumption that Web connectivity is available when required and that the patient is actively involved in his or her own care has also been made. The final assumption is that the EMT, pharmacist, and clinician, all have the proper credentials and permissions to

update the patient's EHR. Upon conclusion of discussing the scenarios the likelihood of an individual with a without an EHR experiencing an ADE will be compare/contrasted.

1. Patients without an EHR

As depicted in Figure 36, if the patient does not have an EHR, he and she is given a direct-encoded QR code upon his or her initial visit to his or her clinician. The clinician initially scans all the medication that the patient is taking in order to populate the patient drug list for the QR code. The QR code is then printed out and given to the patient. The QR code can also be sent electronically to the patient via email or text. If the patient does not have a clinician, the assumption is that the patient is actively involved in his or her own care, and would have obtained a direct-encoded QR code on his or her own.

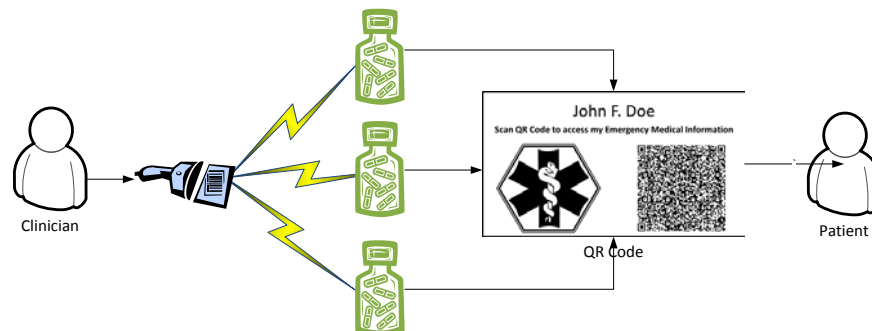


Figure 36. Population of patient drug list on a direct-encoded QR code

If a patient needs medical care the procedures depicted in Figure 37 will be followed. The EMTs or clinicians will scan the patient's QR code and will then either scan or look up the medication that they would like to administer to the patient. The smart device used by the clinicians or EMTs will notify them if there are any drug interactions to the current medication the patient is taking to the drug that they would like to prescribe. If the system shows that there is a drug interaction the drug will not be administered. If the system shows that there are no drug interactions, the patient will be administered the drug, and the EMT and

or clinician will create a new QR code in the form of a sticker to place on top of the old one. In this in the scenario where the patient is transferred to a higher level of care by the EMT, the QR code will be updated at that location. The assumption is that the EMT or clinician will have the ability to print out an updated QR code, albeit a temporary one in the form of a sticker.

If the patient is assigned a prescription by his provider, the pharmacist will follow the same procedures shown in Figure 37. The only exception to this is that the physician will not generate new QR code upon administering the job to the patient. The reason the physician follows the same procedures is to provide a second means of verification to ensure that nothing was missed. If the pharmacist notices a drug interaction, he/she will send the patient back to his or her clinician for the prescribing of another drug.

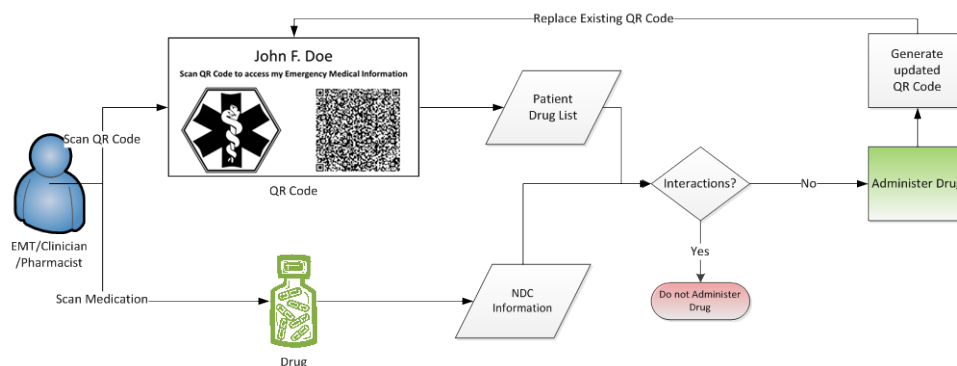


Figure 37. Drug interaction cross-check with a direct-encoded QR code

2. Patients with an EHR

As depicted in Figure 38, if the patient has an EHR, he/she is given a dynamic or hybrid QR code upon his or her initial visit to the clinician. The choice between an indirect-encoded or hybrid QR code is that of the patient. The clinician initially scans all the medication that the patient is taking in order to populate the patient's EHR. The QR code is then generated from the patient drug

list provided in the EHR. The QR code is then printed out and given to the patient. The QR code can also be sent electronically to the patient via email or text.

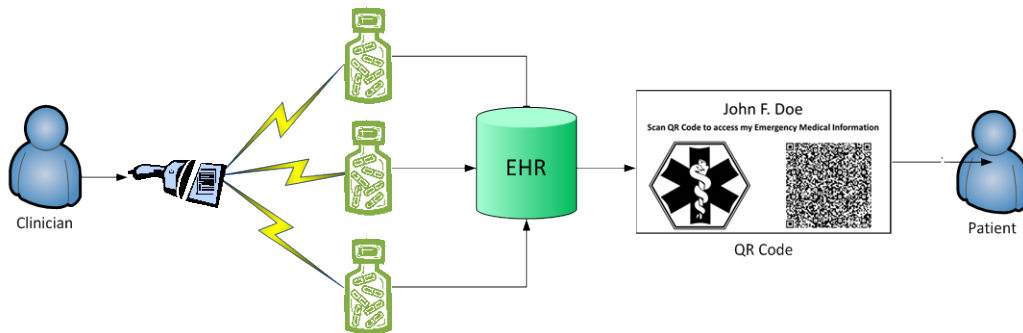


Figure 38. Population of patient drug list on an indirect-encoded/hybrid QR code

Figure 39 depicts the process that would be followed by a clinician during the patient's visit. The clinician will scan the patient's QR code, and will then either scan or look up the medication that they would like to administer to the patient. The smart device used by the clinician will notify them if there are any drug interactions to the current medication the patient is taking to the drug that the clinician would like to prescribe. If the system shows that there is a drug interaction the drug will not be administered. If the system shows that there are no drug interactions, the patient will be administered the drug, and the clinician will update the patient's EHR. If the patient has a hybrid QR code, a new QR code will be generated by the clinician and given to the patient. If the patient has an indirect-encoded QR code no further action will be taken by the clinician at updating EHR.

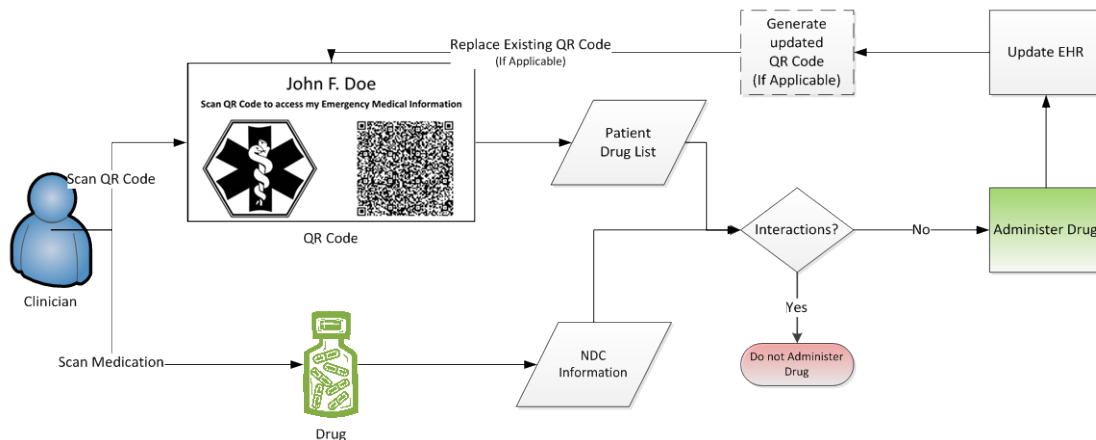


Figure 39. Clinician drug interaction cross-check with an indirect-encoded/hybrid QR code

In the case of an EMT or pharmacist, the procedures depicted in Figure 40 will be followed. The procedures are essentially the same as in Figure 39 with one exception. The EMT or pharmacist will not provide an updated hybrid QR code to the patient. In the EMT scenario, the updated QR code can be generated at the next higher level of care. As stated before, the reason the physician follows the same procedures as to provide a second means of verification to ensure that nothing was missed.

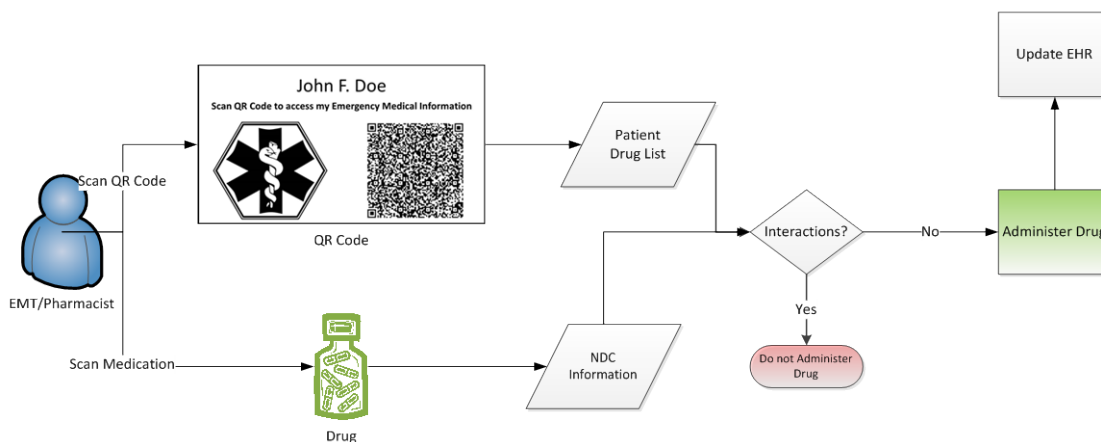


Figure 40. EMT/pharmacy drug interaction cross-check with an indirect-encoded/hybrid QR code

3. Compare/Contrast of ADE Risks for Patients With and Without an EHR

a. Patients without an EHR

The initial creation of the patient drug list for patient without an EHR is critical. The patient has to be very actively involved in his or her care and have significant knowledge of the medication and dosage that he/she is taking. This is required in order for the initial QR code that is generated to be accurate. This is somewhat of a weakness, because all drug interaction checks will be made based on the information provided in initial population of the patient drug list.

In addition, because the patient does not have an EHR, once a new drug is administered it is imperative that a new QR code is generated immediately. There can be situations where this is not possible, the most likely being when the medication is administered by an EMT. More than likely the EMT will not have the time to print out a new QR code for the patient, as that will most likely not be his or her main focus. The obligation would then be on the personnel at the next higher level of care (i.e., clinic or hospital), to ensure that a new QR code is printed.

Also, if the QR code is worn in the form of a necklace or bracelet placing a paper sticker on it may not be best choice. This can be alleviated if the EMT and/or clinician that prepare the replacement QR code on a printer capable of printing quality plastic/metallic QR codes. This however is highly unlikely. A possible way to alleviate this is to have the EMT or clinician send the patient the new QR code via a digital means (email, or text) after which the patient at his or her leisure can get a new QR code generated. The assumption was made that the patient is highly involved in his or her care.

b. Patients with an EHR

As with the patient without an EHR the initial population of the patient drug list to the patient's EHR is critical. Initially, the patient has to be very actively involved in his or her care and have significant knowledge of the

medication and dosage that he/she is taking. The initial QR code and that information in the EHR must be accurate. Once the initial patient drug list is populated, and the patient has an active EHR, the likelihood of ADE's are very low. If the patient has a significant drug list, the benefit of hybrid and indirect-encoded QR codes are that clinician's and EMTs will have access to that data.

Having a hybrid QR code can suffer from the same problems discussed above if the patient desires and/or requires that a new QR code be printed. This is alleviated somewhat however due to the patient's most up-to-date medical information being readily available on his or her EHR. With regards to an EMT, there may be situations in which the EMT does not have time to update the patient's EHR. If that occurs, once the patient is transported to a higher level of care, whatever medication that was given to the patient en route will be then updated in his or her EHR.

In summary, if the procedures presented above are followed by all stakeholders this will result in the significant reduction of ADE's whether or not a patient has an EHR. However, having an EHR provides a more robust overall solution.

C. SWOT ANALYSIS OF USING QR CODES WITH THE NDC AND WITH EHRS

In order to conduct an analysis of our recommendations to use QR codes with the NDC, EHRs, and emergency medical information, strengths, weaknesses, opportunities, and threats (SWOT) analysis has been conducted (see Figure 41).

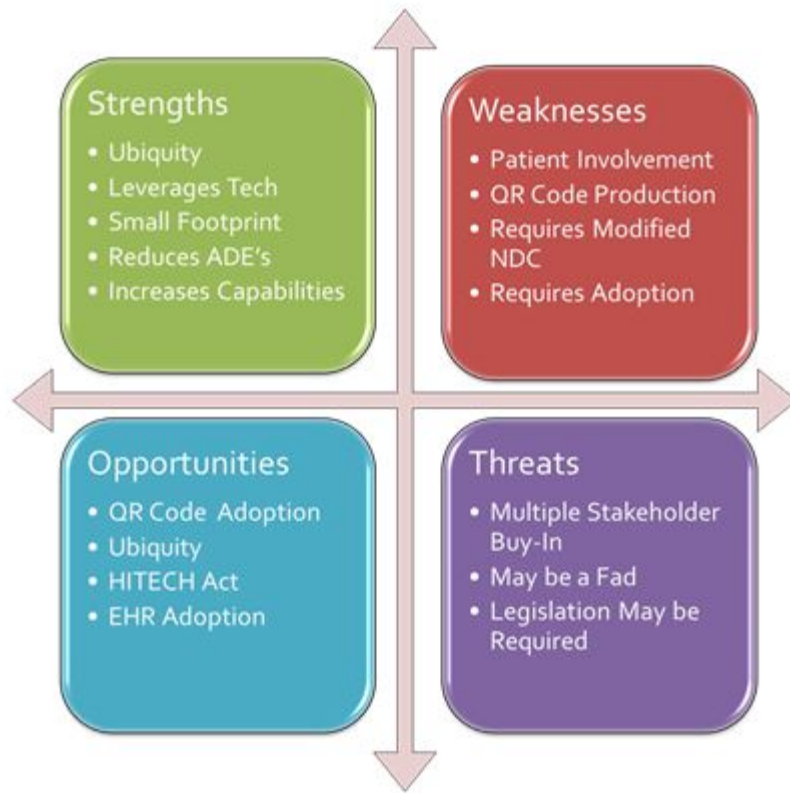


Figure 41. SWOT analysis

1. Strengths

The methodology that has been suggested, utilizes existing technologies (smart phones, laptops, and tablets) that are on target to be ubiquitous. In the years to come it will be commonplace for everyone to have such a device readily available. The technology is easy to understand, and easy to leverage. QR codes allows for the storing of a great amount of data in a small amount of space, it has a very small footprint. Perhaps the major strength of our methodology is that if accepted, it has the opportunity to significantly reduce the amount of ADE's. Our methodology provides increased capabilities to providers and first responders while creating an advantage to the patient as well. This allows for the patient to be more involved in his or her care and provides him or her with a significant value at a minimal cost.

2. Weaknesses

For the suggestions to be successful, it requires significant patient involvement. With regards to the direct-encoded QR codes, the patient would have to ensure that the information stored on the code remained up-to-date. In addition in some instances Web connectivity may be required, and a few additional steps may need to be taken in order to ensure ADE reduction. Another weakness to our suggestion is that it requires the production of a document (the QR code), and some may feel that it is more cost-effective to stay with the status quo. Our methodology also relies on industry adoption, specifically on the modified NDC. This requires a cultural shift that may not be readily accepted by industry. Finally although not required, the use of an EHR in conjunction with QR codes provides for the greatest benefit.

3. Opportunities

The increased industry adoption of QR codes provides the greatest opportunity for success of our methodology. In addition, the ubiquity of QR codes, coupled with the ubiquity of smart devices provides a unique opportunity for industry adoption. In addition, because the U.S. HITECH Act promotes the adoption of EHRs and studies have shown an increased physician adoption of EHRs, this is a significant opportunity (Hing & Hsiao, 2012). An additional study also shows that the adoption of EHR systems among hospitals is at 85 percent (Charles et al., 2013). For these reasons, the opportunity exists for our methodology to be successful.

4. Threats

Perhaps the greatest threat to our methodology is that it requires the buy-in from multiple stakeholders. Stakeholders such as clinicians, providers, EMTs, family members, and patients must believe in this idea for it to succeed. Another threat is that of the QR code itself. If QR codes are just a passing fad, individuals may not want to use them in a few years. Also, for the NDC carrier to be modified it may require legislation, and that perhaps is the greatest threat.

VI. CONCLUSIONS AND RECOMMENDATIONS FOR FUTURE RESEARCH

A. THESIS SUMMARY AND CONCLUSIONS

The primary objective of this thesis was to research and propose a possible solution for decreasing adverse drug events through increasing the efficacy of the National Drug Code, and improving drug management by way of a barcode technology. We proposed that one solution to improve drug management was to provide a better means of accessing emergency medical information. After researching several barcode options, we chose the QR code as the best possible solution because of its data capacity and its ubiquity. One of our main concerns was the hardware used to access the QR code, and we discovered that the most common types of devices on the market capable of accessing QR codes are mobile devices.

We believe that the QR code is the best choice to replace the one-dimensional national drug code, and its capabilities extend beyond carrying an 11-digit number. Our original goal for replacing the current National Drug Code with a QR code was to extend access of the 11-digit number beyond the pharmaceutical industry in hopes of increasing human involvement in drug management. By improving drug management, we believe that our research indicates the potential for decreasing ADEs.

Since the QR code has the ability to store more information, one of the goals of increasing the efficacy of the National Drug Code would be to store information about the particular drug related to that code. This information would provide patients, providers, and non-providers involved in patient care quick and resourceful information to improve drug management.

We also believe that the QR code provides the best way for patients to store their emergency medical information in order to help first responders have a better understanding of a patient's medical condition. If a first responder has a

mobile device capable of reading a QR code, he or she can quickly scan it and gain access to medical information. This medical information includes a current list of drugs that the patient is taking and could prevent the administering of emergency medication that can cause adverse drug events, or adverse allergic reactions.

B. FUTURE RESEARCH

This thesis focused primarily on the use of QR codes with the National Drug Code, as well as to aid in the access of emergency medical information. Further research is required on the implementation of our recommendations, QR code encryption and password protection, and the security configurations for using a QR code to access an online EHR.

1. Implement Recommendations to Test if ADEs are Reduced.

On a small scale, our recommendation should be implemented and data collected on its use in the healthcare field (e.g., pharmaceutical industry, emergency medicine, hospitalizations, and ambulatory care) in order to verify if ADEs are reduced from this method.

2. QR Code Encryption and Password Protection

Encryption and password protection will be required if any personally identifiable information such as medical information about an individual is placed on QR code. In addition, security considerations for using a QR code to access an online electronic health record should also be researched.

APPENDIX VERSION AND MAXIMUM DATA CAPACITY TABLE

The symbol versions of the QR code range from versions 1–40. Each version increases by four additional modules on each side (Barcode Library, 2010).

Version	Modules	ECC Level	Data bits	Numeric	Alphanumeric	Binary	Kanji
1	21x21	L	152	41	25	17	10
		M	128	34	20	14	8
		Q	104	27	16	11	7
		H	72	17	10	7	4
2	25x25	L	272	77	47	32	20
		M	224	63	38	26	16
		Q	176	48	29	20	12
		H	128	34	20	14	8
3	29x29	L	440	127	77	53	32
		M	352	101	61	42	26
		Q	272	77	47	32	20
		H	208	58	35	24	15
4	33x33	L	640	187	114	78	48
		M	512	149	90	62	38
		Q	384	111	67	46	28
		H	288	82	50	34	21
5	37x37	L	864	255	154	106	65
		M	688	202	122	84	52
		Q	496	144	87	60	37
		H	368	106	64	44	27
6	41x41	L	1,088	322	195	134	82
		M	864	255	154	106	65
		Q	608	178	108	74	45
		H	480	139	84	58	36
7	45x45	L	1,248	370	224	154	95
		M	992	293	178	122	75
		Q	704	207	125	86	53
		H	528	154	93	64	39
8	49x49	L	1,552	461	279	192	118
		M	1,232	365	221	152	93
		Q	880	259	157	108	66
		H	688	202	122	84	52
9	53x53	L	1,856	552	335	230	141
		M	1,456	432	262	180	111
		Q	1,056	312	189	130	80
		H	800	235	143	98	60
10	57x57	L	2,192	652	395	271	167
		M	1,728	513	311	213	131
		Q	1,232	364	221	151	93
		H	976	288	174	119	74

Version	Modules	ECC Level	Data bits	Numeric	Alphanumeric	Binary	Kanji
11	61x61	L	2,592	772	468	321	198
		M	2,032	604	366	251	155
		Q	1,440	427	259	177	109
		H	1,120	331	200	137	85
12	65x65	L	2,960	883	535	367	226
		M	2,320	691	419	287	177
		Q	1,648	489	296	203	125
		H	1,264	374	227	155	96
13	69x69	L	3,424	1,022	619	425	262
		M	2,672	796	483	331	204
		Q	1,952	580	352	241	149
		H	1,440	427	259	177	109
14	73x73	L	3,688	1,101	667	458	282
		M	2,920	871	528	362	223
		Q	2,088	621	376	258	159
		H	1,576	468	283	194	120
15	77x77	L	4,184	1,250	758	520	320
		M	3,320	991	600	412	254
		Q	2,360	703	426	292	180
		H	1,784	530	321	220	136
16	81x81	L	4,712	1,408	854	586	361
		M	3,624	1,082	656	450	277
		Q	2,600	775	470	322	198
		H	2,024	602	365	250	154
17	85x85	L	5,176	1,548	938	644	397
		M	4,056	1,212	734	504	310
		Q	2,936	876	531	364	224
		H	2,264	674	408	280	173
18	89x89	L	5,768	1,725	1,046	718	442
		M	4,504	1,346	816	560	345
		Q	3,176	948	574	394	243
		H	2,504	746	452	310	191
19	93x93	L	6,360	1,903	1,153	792	488
		M	5,016	1,500	909	624	384
		Q	3,560	1,063	644	442	272
		H	2,728	813	493	338	208
20	97x97	L	6,888	2,061	1,249	858	528
		M	5,352	1,600	970	666	410
		Q	3,880	1,159	702	482	297
		H	3,080	919	557	382	235

Version	Modules	ECC Level	Data bits	Numeric	Alphanumeric	Binary	Kanji
21	101x101	L	7,456	2,232	1,352	929	572
		M	5,712	1,708	1,035	711	438
		Q	4,096	1,224	742	509	314
		H	3,248	969	587	403	248
22	105x105	L	8,048	2,409	1,460	1,003	618
		M	6,256	1,872	1,134	779	480
		Q	4,544	1,358	823	565	348
		H	3,536	1,056	640	439	270
23	109x109	L	8,752	2,620	1,588	1,091	672
		M	6,880	2,059	1,248	857	528
		Q	4,912	1,468	890	611	376
		H	3,712	1,108	672	461	284
24	113x113	L	9,392	2,812	1,704	1,171	721
		M	7,312	2,188	1,326	911	561
		Q	5,312	1,588	963	661	407
		H	4,112	1,228	744	511	315
25	117x117	L	10,208	3,057	1,853	1,273	784
		M	8,000	2,395	1,451	997	614
		Q	5,744	1,718	1,041	715	440
		H	4,304	1,286	779	535	330
26	121x121	L	10,960	3,283	1,990	1,367	842
		M	8,496	2,544	1,542	1,059	652
		Q	6,032	1,804	1,094	751	462
		H	4,768	1,425	864	593	365
27	125x125	L	11,744	3,514	2,132	1,465	902
		M	9,024	2,701	1,637	1,125	692
		Q	6,464	1,933	1,172	805	496
		H	5,024	1,501	910	625	385
28	129x129	L	12,248	3,669	2,223	1,528	940
		M	9,544	2,857	1,732	1,190	732
		Q	6,968	2,085	1,263	868	534
		H	5,288	1,581	958	658	405
29	133x133	L	13,048	3,909	2,369	1,628	1,002
		M	10,136	3,035	1,839	1,264	778
		Q	7,288	2,181	1,322	908	559
		H	5,608	1,677	1,016	698	430
30	137x137	L	13,880	4,158	2,520	1,732	1,066
		M	10,984	3,289	1,994	1,370	843
		Q	7,880	2,358	1,429	982	604
		H	5,960	1,782	1,080	742	457

Version	Modules	ECC Level	Data bits	Numeric	Alphanumeric	Binary	Kanji
31	141x141	L	14,744	4,417	2,677	1,840	1132
		M	11,640	3,486	2,113	1,452	894
		Q	8,264	2,473	1,499	1,030	634
		H	6,344	1,897	1,150	790	486
32	145x145	L	15,640	4,686	2,840	1,952	1,201
		M	12,328	3,693	2,238	1,538	947
		Q	8,920	2,670	1,618	1,112	684
		H	6,760	2,022	1,226	842	518
33	149x149	L	16,568	4,965	3,009	2,068	1,273
		M	13,048	3,909	2,369	1,628	1,002
		Q	9,368	2,805	1,700	1,168	719
		H	7,208	2,157	1,307	898	553
34	153x153	L	17,528	5,253	3,183	2,188	1,347
		M	13,800	4,134	2,506	1,722	1,060
		Q	9,848	2,949	1,787	1,228	756
		H	7,688	2,301	1,394	958	590
35	157x157	L	18,448	5,529	3,351	2,303	1,417
		M	14,496	4,343	2,632	1,809	1,113
		Q	10,288	3,081	1,867	1,283	790
		H	7,888	2,361	1,431	983	605
36	161x161	L	19,472	5,836	3,537	2,431	1,496
		M	15,312	4,588	2,780	1,911	1,176
		Q	10,832	3,244	1,966	1,351	832
		H	8,432	2,524	1,530	1,051	647
37	165x165	L	20,528	6,153	3,729	2,563	1,577
		M	15,936	4,775	2,894	1,989	1,224
		Q	11,408	3,417	2,071	1,423	876
		H	8,768	2,625	1,591	1,093	673
38	169x169	L	21,616	6,479	3,927	2,699	1,661
		M	16,816	5,039	3,054	2,099	1,292
		Q	12,016	3,599	2,181	1,499	923
		H	9,136	2,735	1,658	1,139	701
39	173x173	L	22,496	6,743	4,087	2,809	1,729
		M	17,728	5,313	3,220	2,213	1,362
		Q	12,656	3,791	2,298	1,579	972
		H	9,776	2,927	1,774	1,219	750
40	177x177	L	23,648	7,089	4,296	2,953	1,817
		M	18,672	5,596	3,391	2,331	1,435
		Q	13,328	3,993	2,420	1,663	1,024
		H	10,208	3,057	1,852	1,273	784

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